PTO Form 1960 (Rev 10/2011)
OMB No. 0651-0050 (Exp 09/20/2020)

Request for Reconsideration after Final Action

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	87348251
LAW OFFICE ASSIGNED	LAW OFFICE 118
MARK SECTION	
MARK FILE NAME	https://tmng-al.uspto.gov/resting2/api/img/87348251/large
LITERAL ELEMENT	ATHENEX
STANDARD CHARACTERS	NO
USPTO-GENERATED IMAGE	NO
COLOR(S) CLAIMED (If applicable)	Color is not claimed as a feature of the mark.
DESCRIPTION OF THE MARK (and Color Location, if applicable)	The mark consists of the word "ATHENEX", with a stylized "A" wherein the crossing line of the letter "A" is a curved line that is extended under the entire mark. The letter "X" has a curve in the opposing direction.
GOODS AND/OR SERVICES SECTION (current)	
INTERNATIONAL CLASS	005
DESCRIPTION	
Prescription pharmaceutical products for a variety of diseases	
FILING BASIS	Section 1(a)
FIRST USE ANYWHERE DATE	At least as early as 11/02/2015
FIRST USE IN COMMERCE DATE	At least as early as 02/08/2017
GOODS AND/OR SERVICES SECTION (proposed)	
INTERNATIONAL CLASS	005
TRACKED TEXT DESCRIPTION	
~~Prescription pharmaceutical products for a variety of diseases~~; House mark for pharmaceuticals directed to treatment of diseases and disorders affecting the circulatory system, digestive system, excretory system, endocrine system, integumentary system/exocrine system, immune system and lymphatic system, muscular system, nervous system, renal system and urinary system, reproductive system, respiratory system, skeletal system, impacting the blood, brain, heart, lungs, kidneys, stomach, liver, pancreas, mammary glands, ovaries, uterus, testes, bladder, rectum, large intestine, small intestine, gall bladder, hair, skin, nails, muscles, bones, joints, tendons, spine, thymus, thyroid, lymph nodes, spleen, eyes, nose, trachea, esophagus, including anti-infectives, anti-emetics, narcotics/analgesics, pharmaceutical preparations for the treatment of infectious diseases, pharmaceutical preparations for the treatment of dermatological conditions, pharmaceutical products for the treatment of cancer, anesthesia and sedatives, pain relief, antiinflamatory preparations, antiepileptic agents, muscle relaxants	
FINAL DESCRIPTION	
House mark for pharmaceuticals directed to treatment of diseases and disorders affecting the circulatory system, digestive system, excretory system, endocrine system, integumentary system/exocrine system, immune system and lymphatic system, muscular system, nervous system, renal system and urinary system, reproductive system, respiratory system, skeletal system, impacting the blood, brain, heart, lungs, kidneys, stomach, liver, pancreas, mammary glands, ovaries, uterus, testes, bladder, rectum, large intestine, small intestine, gall bladder, hair, skin, nails, muscles, bones, joints, tendons, spine, thymus, thyroid, lymph nodes, spleen, eyes, nose, trachea, esophagus, including anti-infectives, anti-emetics, narcotics/analgesics, pharmaceutical preparations for the treatment of infectious diseases, pharmaceutical preparations for the	

treatment of dermatological conditions, pharmaceutical products for the treatment of cancer, anesthesia and sedatives, pain relief, antiinflamatory preparations, antiepileptic agents, muscle relaxants	
FILING BASIS	Section 1(a)
FIRST USE ANYWHERE DATE	At least as early as 11/02/2015
FIRST USE IN COMMERCE DATE	At least as early as 02/08/2017
ADDITIONAL STATEMENTS SECTION	
MISCELLANEOUS STATEMENT	The following is in response to the Office Action issued June 14, 2019. In accordance with the Trademark Examining Attorney's requirements, Applicant has attached as Exhibit A catalog and insert pages that support its use of its ATHENEX LOGO mark as a house mark. It is respectfully requested that the application proceed to publication.
MISCELLANEOUS FILE NAME(S)	
ORIGINAL PDF FILE	mis-3898219243-20191212144107485440_._EXHIBIT_A_-.pdf
CONVERTED PDF FILE(S) (86 pages)	\\TICRS\EXPORT17\IMAGEOUT17\873\482\87348251\xml11\RFR0002.JPG
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ATTORNEY SECTION (current)	
NAME	Jacqueline M. Lesser
ATTORNEY BAR MEMBERSHIP NUMBER	NOT SPECIFIED
YEAR OF ADMISSION	NOT SPECIFIED
U.S. STATE/ COMMONWEALTH/ TERRITORY	NOT SPECIFIED
FIRM NAME	BAKER & HOSTETLER LLP
INTERNAL ADDRESS	CIRA CENTRE, 12TH FLOOR
STREET	2929 ARCH STREET
CITY	PHILADELPHIA
STATE	Pennsylvania
POSTAL CODE	19104-2891
COUNTRY	US
PHONE	215.568.3100

FAX	215.568.3439
EMAIL	BHIPDocket@bakerlaw.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
DOCKET/REFERENCE NUMBER	099927.00038
ATTORNEY SECTION (proposed)	
NAME	Jacqueline M. Lesser
ATTORNEY BAR MEMBERSHIP NUMBER	XXX
YEAR OF ADMISSION	XXXX
U.S. STATE/ COMMONWEALTH/ TERRITORY	XX
FIRM NAME	BAKER & HOSTETLER LLP
INTERNAL ADDRESS	CIRA CENTRE, 12TH FLOOR
STREET	2929 ARCH STREET
CITY	PHILADELPHIA
STATE	Pennsylvania
POSTAL CODE	19104-2891
COUNTRY	United States
PHONE	215.568.3100
FAX	215.568.3439
EMAIL	BHIPDocket@bakerlaw.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
DOCKET/REFERENCE NUMBER	099927.00038
OTHER APPOINTED ATTORNEY	Nancy Rubner Frandsen, Kevin M. Bovard, Lesley M. Grossberg, Lisa Bollinger Gehman, and Savannah Merceus
CORRESPONDENCE SECTION (current)	
NAME	JACQUELINE M. LESSER
FIRM NAME	BAKER & HOSTETLER LLP
INTERNAL ADDRESS	CIRA CENTRE, 12TH FLOOR
STREET	2929 ARCH STREET
CITY	PHILADELPHIA
STATE	Pennsylvania
POSTAL CODE	19104-2891
COUNTRY	US
PHONE	215.568.3100
FAX	215.568.3439
EMAIL	BHIPDocket@bakerlaw.com; jlesser@bakerlaw.com; jmbarr@bakerlaw.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
DOCKET/REFERENCE NUMBER	099927.00038
CORRESPONDENCE SECTION (proposed)	

NAME	Jacqueline M. Lesser
FIRM NAME	BAKER & HOSTETLER LLP
INTERNAL ADDRESS	CIRA CENTRE, 12TH FLOOR
STREET	2929 ARCH STREET
CITY	PHILADELPHIA
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AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
DOCKET/REFERENCE NUMBER	099927.00038
SIGNATURE SECTION	
RESPONSE SIGNATURE	/Jacqueline M. Lesser/
SIGNATORY'S NAME	Jacqueline M. Lesser
SIGNATORY'S POSITION	Attorney of record, PA bar member
SIGNATORY'S PHONE NUMBER	215.564.2155
DATE SIGNED	12/13/2019
AUTHORIZED SIGNATORY	YES
CONCURRENT APPEAL NOTICE FILED	NO
FILING INFORMATION SECTION	
SUBMIT DATE	Fri Dec 13 15:07:47 EST 2019
TEAS STAMP	USPTO/RFR-XX.XX.XXX.XXX-2 0191213150747811173-87348 251-70045e6d2a792d9fd2998 5412dc50cc5f03c3f10191820 ae3b2571113b63cc1-N/A-N/A -20191212144107485440

Request for Reconsideration after Final Action

To the Commissioner for Trademarks:

Application serial no. **87348251** ATHENEX (Stylized and/or with Design, see https://tmng-al.uspto.gov/resting2/api/img/87348251/large) has been amended as follows:

CLASSIFICATION AND LISTING OF GOODS/SERVICES

Applicant proposes to amend the following class of goods/services in the application:

Current: Class 005 for Prescription pharmaceutical products for a variety of diseases
Original Filing Basis:
Filing Basis: Section 1(a), Use in Commerce: The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 11/02/2015 and first used in commerce at least as early as 02/08/2017 , and is now in use in such commerce.

Proposed:
Tracked Text Description: ~~Prescription pharmaceutical products for a variety of diseases~~; House mark for pharmaceuticals directed to treatment of diseases and disorders affecting the circulatory system, digestive system, excretory system, endocrine system, integumentary system/exocrine system, immune system and lymphatic system, muscular system, nervous system, renal system and urinary system, reproductive system, respiratory system, skeletal system, impacting the blood, brain, heart, lungs, kidneys, stomach, liver, pancreas, mammary glands, ovaries, uterus, testes, bladder, rectum, large intestine, small intestine, gall bladder, hair, skin, nails, muscles, bones, joints, tendons, spine, thymus, thyroid, lymph nodes, spleen, eyes, nose, trachea, esophagus, including anti-infectives, anti-emetics, narcotics/analgesics, pharmaceutical preparations for the treatment of infectious diseases, pharmaceutical preparations for the treatment of dermatological conditions, pharmaceutical products for the treatment of cancer, anesthesia and sedatives, pain relief, antiinflamatory preparations, antiepileptic agents, muscle relaxants

Class 005 for House mark for pharmaceuticals directed to treatment of diseases and disorders affecting the circulatory system, digestive system, excretory system, endocrine system, integumentary system/exocrine system, immune system and lymphatic system, muscular system, nervous system, renal system and urinary system, reproductive system, respiratory system, skeletal system, impacting the blood, brain, heart, lungs, kidneys, stomach, liver, pancreas, mammary glands, ovaries, uterus, testes, bladder, rectum, large intestine, small intestine, gall bladder, hair, skin, nails, muscles, bones, joints, tendons, spine, thymus, thyroid, lymph nodes, spleen, eyes, nose, trachea, esophagus, including anti-infectives, anti-emetics, narcotics/analgesics, pharmaceutical preparations for the treatment of infectious diseases, pharmaceutical preparations for the treatment of dermatological conditions, pharmaceutical products for the treatment of cancer, anesthesia and sedatives, pain relief, antiinflamatory preparations, antiepileptic agents, muscle relaxants
Filing Basis: Section 1(a), Use in Commerce: The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 11/02/2015 and first used in commerce at least as early as 02/08/2017 , and is now in use in such commerce.
The applicant's current attorney information: Jacqueline M. Lesser. Jacqueline M. Lesser of BAKER & HOSTETLER LLP, is located at

CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, Pennsylvania 19104-2891
US

The docket/reference number is 099927.00038.

The phone number is 215.568.3100.

The fax number is 215.568.3439.

The email address is BHIPDocket@bakerlaw.com

The applicants proposed attorney information: Jacqueline M. Lesser. Other appointed attorneys are Nancy Rubner Frandsen, Kevin M. Bovard, Lesley M. Grossberg, Lisa Bollinger Gehman, and Savannah Merceus. Jacqueline M. Lesser of BAKER & HOSTETLER LLP, is a member of the XX bar, admitted to the bar in XXXX, bar membership no. XXX, and the attorney(s) is located at

CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, Pennsylvania 19104-2891
United States

The docket/reference number is 099927.00038.

The phone number is 215.568.3100.

The fax number is 215.568.3439.

The email address is BHIPDocket@bakerlaw.com

Jacqueline M. Lesser submitted the following statement: The attorney of record is an active member in good standing of the bar of the highest court of a U.S. state, the District of Columbia, or any U.S. Commonwealth or territory.

The applicant's current correspondence information: JACQUELINE M. LESSER. JACQUELINE M. LESSER of BAKER & HOSTETLER LLP, is located at

CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, Pennsylvania 19104-2891
US

The docket/reference number is 099927.00038.

The phone number is 215.568.3100.

The fax number is 215.568.3439.

The email address is BHIPDocket@bakerlaw.com; jlesser@bakerlaw.com; jmbarr@bakerlaw.com

The applicants proposed correspondence information: Jacqueline M. Lesser. Jacqueline M. Lesser of BAKER & HOSTETLER LLP, is located at

CIRA CENTRE, 12TH FLOOR
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The docket/reference number is 099927.00038.

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The email address is BHIPDocket@bakerlaw.com; jlesser@bakelaw.com; jmbarr@bakerlaw.com

ADDITIONAL STATEMENTS

Miscellaneous Statement

The following is in response to the Office Action issued June 14, 2019. In accordance with the Trademark Examining Attorney's requirements, Applicant has attached as Exhibit A catalog and insert pages that support its use of its ATHENEX LOGO mark as a house mark. It is respectfully requested that the application proceed to publication.

Original PDF file:

mis-3898219243-20191212144107485440_._EXHIBIT_A_-.pdf

Converted PDF file(s) (86 pages)

Miscellaneous File1
Miscellaneous File2
Miscellaneous File3
Miscellaneous File4
Miscellaneous File5
Miscellaneous File6
Miscellaneous File7
Miscellaneous File8
Miscellaneous File9
Miscellaneous File10
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Miscellaneous File81

Miscellaneous File82
Miscellaneous File83
Miscellaneous File84
Miscellaneous File85
Miscellaneous File86

SIGNATURE(S)
Request for Reconsideration Signature
Signature: /Jacqueline M. Lesser/ Date: 12/13/2019
Signatory's Name: Jacqueline M. Lesser
Signatory's Position: Attorney of record, PA bar member

Signatory's Phone Number: 215.564.2155

The signatory has confirmed that he/she is a U.S.-licensed attorney who is an active member in good standing of the bar of the highest court of a U.S. state (including the District of Columbia and any U.S. Commonwealth or territory); and he/she is currently the owner's/holder's attorney or an associate thereof; and to the best of his/her knowledge, if prior to his/her appointment another U.S.-licensed attorney not currently associated with his/her company/firm previously represented the owner/holder in this matter: the owner/holder has revoked their power of attorney by a signed revocation or substitute power of attorney with the USPTO; the USPTO has granted that attorney's withdrawal request; the owner/holder has filed a power of attorney appointing him/her in this matter; or the owner's/holder's appointed U.S.-licensed attorney has filed a power of attorney appointing him/her as an associate attorney in this matter.

The applicant is not filing a Notice of Appeal in conjunction with this Request for Reconsideration.

Mailing Address: JACQUELINE M. LESSER
BAKER & HOSTETLER LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, Pennsylvania 19104-2891
Mailing Address: Jacqueline M. Lesser
BAKER & HOSTETLER LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, Pennsylvania 19104-2891

Serial Number: 87348251
Internet Transmission Date: Fri Dec 13 15:07:47 EST 2019
TEAS Stamp: USPTO/RFR-XX.XX.XXX.XXX-2019121315074781
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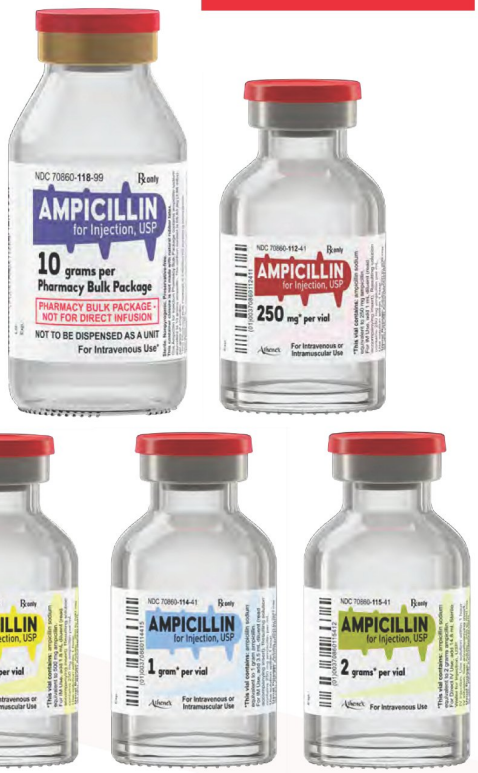
c50cc5f03c3f10191820ae3b2571113b63cc1-N/
A-N/A-20191212144107485440

EXHIBIT A

Ampicillin
for Injection, USP

250 mg per vial	|	NDC 70860-112-15
500 mg per vial	|	NDC 70860-113-15
1 gram per vial	|	NDC 70860-114-15
2 grams per vial	|	NDC 70860-115-26
10 grams per vial	|	NDC 70860-118-99



- **ATHENEX AccuraSEE℠ PACKAGING AND LABELING**
- **BIG, BOLD AND BRIGHT —**
  TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT
- **DIFFERENTIATION IN EVERY LABEL,**
  DESIGNED TO HELP REDUCE MEDICATION ERRORS

THE NEXT GENERATION OF PHARMACY INNOVATION

Ampicillin

for Injection, USP

250 mg

NDC 70860-112-15

250 mg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	250 mg per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

500 mg

NDC 70860-113-15

500 mg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	500 mg per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

1 g

NDC 70860-114-15

1 gram per vial

DESCRIPTION	Glass Vial
CONCENTRATION	1 gram per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

2 g

NDC 70860-115-26

2 gram per vial

DESCRIPTION	Glass Vial
CONCENTRATION	2 grams per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

10 g

NDC 70860-118-99

10 grams per vial

DESCRIPTION	Pharmacy Bulk Package
CONCENTRATION	10 grams per vial
CLOSURE	32 mm
UNIT OF SALE	1 bottle
BAR CODED	Yes

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Athenex

Azithromycin
for Injection, USP

500 mg per vial | NDC 70860-100-10

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THE NEXT GENERATION OF PHARMACY INNOVATION

Azithromycin
for Injection, USP

500 mg

NDC 70860-100-10
500 mg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	500 mg per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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Busulfan
Injection

60 mg per 10 mL | NDC 70860-216-10

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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR BUSULFAN INJECTION, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Busulfan

Injection

60 mg

NDC 70860-216-10
60 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	6 mg per mL
CLOSURE	20 mm
UNIT OF SALE	8 vials
BAR CODED	Yes

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BUSULFAN Injection

INDICATION AND USAGE

- Busulfan injection is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.

IMPORTANT SAFETY INFORMATION

WARNING: MYELOSUPPRESSION

BUSULFAN INJECTION CAUSES SEVERE AND PROLONGED MYELOSUPPRESSION AT THE RECOMMENDED DOSAGE. HEMATOPOIETIC PROGENITOR CELL TRANSPLANTATION IS REQUIRED TO PREVENT POTENTIALLY FATAL COMPLICATIONS OF THE PROLONGED MYELOSUPPRESSION

CONTRAINDICATIONS

- Busulfan is contraindicated in patients with a history of hypersensitivity to any of its components.

WARNINGS and PRECAUTIONS

- **Myelosuppression:** The most frequent serious consequence of treatment with busulfan at the recommended dose and schedule is prolonged myelosuppression, occurring in all patients (100%). Severe granulocytopenia, thrombocytopenia, anemia, or any combination thereof may develop. Hematopoietic progenitor cell transplantation is required to prevent potentially fatal complications. Monitor complete blood counts, including white blood cell differentials, and quantitative platelet counts daily during treatment. Use antibiotic therapy and platelet and red blood cell support when medically indicated.
- **Seizures:** Seizures have been reported in patients receiving high-dose oral busulfan at doses producing plasma drug levels similar to those achieved following the recommended dosage of Busulfan Injection. Initiate phenytoin therapy or any other alternative anti-convulsant prophylactic therapy (e.g., benzodiazepines, valproic acid or levetiracetam) prior to Busulfan Injection treatment. Use caution when administering the recommended dose of Busulfan Injection to patients with a history of a seizure disorder or head trauma or who are receiving other potentially epileptogenic drugs.
- **Hepatic Veno-Occlusive Disease (HVOD):** High busulfan area under the plasma concentration vs. time curve (AUC) values (greater than 1,500 μM•min) may be associated with an increased risk of developing HVOD. Patients who have received prior radiation therapy, greater than or equal to three cycles of chemotherapy, or a prior progenitor cell transplant may be at an increased risk of developing HVOD. Monitor serum transaminases, alkaline phosphatase, and bilirubin daily through BMT Day +28 to detect hepatotoxicity, which may herald the onset of HVOD.
- **Embryo-fetal Toxicity:** Busulfan Injection can cause fetal harm when administered to a pregnant woman based on animal data. Advise pregnant women of the potential risk to a fetus. Busulfan Injection may damage spermatozoa and testicular tissue. Advise females and males of reproductive potential to use effective contraception during and after treatment with Busulfan Injection.
- **Cardiac Tamponade:** Cardiac tamponade has been reported in pediatric patients with thalassemia who received high doses of oral busulfan and cyclophosphamide as the preparatory regimen for hematopoietic progenitor cell transplantation. Abdominal pain and vomiting preceded the tamponade in most patients. Monitor for signs and symptoms, promptly evaluate and treat if cardiac tamponade is suspected.
- **Bronchopulmonary Dysplasia:** Bronchopulmonary dysplasia with pulmonary fibrosis is a rare but serious complication following chronic busulfan therapy. The average onset of symptoms is 4 years after therapy (range 4 months to 10 years).
- **Cellular Dysplasia:** Busulfan Injection may cause cellular dysplasia in many organs. The resulting cytologic abnormalities may be severe enough to cause difficulty in the interpretation of exfoliative cytologic examinations of the lungs, bladder, breast and the uterine cervix.
- **Lactation:** Advise women to discontinue breastfeeding because of the potential for tumorigenicity shown for busulfan in animal and human studies.

ADVERSE REACTIONS

- The most common adverse reactions (incidence greater than 60%) were myelosuppression, nausea, stomatitis, vomiting, anorexia, diarrhea, insomnia, fever, headache, hypomagnesemia, abdominal pain, anxiety, hyperglycemia, and hypokalemia.

OVERDOSAGE

- There is no known antidote to Busulfan Injection other than hematopoietic progenitor cell transplantation. In the absence of hematopoietic progenitor cell transplantation, the recommended dosage for Busulfan Injection would constitute an overdose of busulfan. The principal toxic effect is profound bone marrow hypoplasia/aplasia and pancytopenia, but the central nervous system, liver, lungs, and gastrointestinal tract may be affected. Monitor hematologic status closely and institute vigorous supportive measures as medically indicated. Dialysis should be considered in the case of overdose.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for BUSULFAN Injection.

AccuraSEE™ PACKAGING & LABELING

Athenex

Caspofungin
Acetate for Injection

50 mg per vial | NDC 70860-106-10

70 mg per vial | NDC 70860-107-10

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THE NEXT GENERATION OF PHARMACY INNOVATION

Caspofungin
Acetate for Injection

50 mg

NDC 70860-106-10
50 mg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	50 mg per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

70 mg

NDC 70860-107-10
70 mg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	70 mg per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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CISplatin
Injection

50 mg per 50 mL | NDC 70860-206-50

100 mg per 100 mL | NDC 70860-206-51

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THE NEXT GENERATION OF PHARMACY INNOVATION

CISplatin
Injection

50 mg

NDC 70860-206-50
50 mg per 50 mL

DESCRIPTION	Amber Vial
CONCENTRATION	1 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

100 mg

NDC 70860-206-51
100 mg per 100 mL

DESCRIPTION	Amber Vial
CONCENTRATION	1 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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CISPLATIN Injection

INDICATION AND USAGE

- Cisplatin Injection is indicated in established combination therapy with other approved chemotherapeutic agents in patients with metastatic testicular tumors who have already received appropriate surgical and/or radiotherapeutic procedures.
- Cisplatin Injection is indicated in established combination therapy with other approved chemotherapeutic agents in patients with metastatic ovarian tumors who have already received appropriate surgical and/or radiotherapeutic procedures. An established combination consists of cisplatin and cyclophosphamide. Cisplatin Injection, as a single agent, is indicated as secondary therapy In patients with metastatic ovarian tumors refractory to standard chemotherapy who have not pr viously received Cisplatin Injection therapy.
- Cisplatin Injection is indicated as a single agent for patients with transitional cell bladder cancer which is no longer amenable to local treatments, such as surgery and/or radiotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS

Cisplatin should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.

Cumulative renal toxicity associated with cisplatin is severe. Other major dose-related toxicities are myelosuppression, nausea, and vomiting.

Ototoxicity, which may be more pronounced in children, and is manifested by tinnitus, and/or loss of high frequency hearing and occasionally deafness, is significant.

Anaphylactic-like reactions to cispfatin have been reported. Facial edema, bronchoconstriction, tachycardia, and hypotension may occur within minutes of cisplatin administration. Epinephrine, corticosteroids, and antihistamines have been effectively employed to alleviate symptoms.

Exercise caution to prevent inadvertent cisplatin overdose. Doses greater than 100 mg/ m2/ cycle once every 3 to 4 weeks are rarely used. Care must be taken to avoid inadvertent cisplatin overdose due to confusion with carboplatin or prescribing practices that fail to differentiate daily doses from total dose per cycle.

CONTRAINDICATIONS

- Cisplatin is contraindicatedin patients with pre-existing renal impairment. Cisplatin should not be employed in myelosuppressed patients, or in patients with hearing impairment.
- Cisplatin is contraindicated in patients with a history of allergic reactions to cisplatin or other platinum containing compounds.

WARNINGS

- Cisplatin produces cumulative nephrotoxicity which is potentiated by aminoglycoside antibiotics. Serum creatlnine, blood urea nitrogen (BUN), creatinine clearance, and magnesium, sodium, potassi um, and calcium levels should be measured prior to initiating therapy, and prior to each subsequent course. At the recommended dosage, cisplatin should not be given more frequently than once every 3 to 4 weeks. Elderly patients may be more susceptible to nephrotoxicity.
- There are reports of severe neuropathies in patients in whom regimens are employed using higher doses of cisplatin or greater dose frequencies than those recommended. These neuropathies may be irreversible and are seen as paresthesias in a stocking-glove distribution, areflexia , and loss of proprioception and vibratory sensation. Elderly patients may be more susceptible to peripheral neuro pathy. Loss of motor function has also been reported.
- Cisplatin can commonly cause ototoxicity which is cumulative and may be severe . Audiometric testing should be performed prior to initiating therapy and prior to each subsequent dose of drug. All pediatric patients receiving cisplatin sh ould have audiometric testing at baseline, prior to each subsequent dose of drug and for several years post therapy.
- Cisplatin can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Pat ients should be advised to avoid becoming pregnant.
- The development of acute leukemia coincident with the use of cisplatin has been reported. In these reports, cisplatin was generally given in combination with other leukemogenic agents.
- Injection site reactions may occur during the administration of cisplatin. Given the possibility of extravasation, it is recommended to closely monitor the infusion site for possible infiltration during drug administration. A specific treatment for extravasation reactions is unknown at this time.

PRECAUTIONS

- Peripheral blood counts should be monitored weekly. liver function should be monitored periodically. Neurologic examination should also be performed regularly.
- Cisplatin should not be used during nursing.
- Cisplatin should not be given by rapid intravenous injection.
- Pretreatment hydration with 1 to 2 liters of fluid infused for 8 to 12 hours prior to a cisplatin dose is recommended.
- Needles or intravenous sets containing aluminum parts that may come in contact with cisplatin should not be used for preparation or administration because aluminum reacts with cisplatin, causing precipitate formation and a loss of potency.

ADVERSE REACTIONS

- Nephrotoxicity- Dose-related and cumulative renal insufficiency, including acute renal failure, is the major dose-limiting toxicity of cisplatin and is manifested by elevations in BUN and creatinine, serum uric acid and/or a decrease in creatinine clearance.
- Ototoxicity- Manifested by tinnitus a d/or hearing loss in the high frequency range (4, 000 to 8,000 Hz).
- Hematologic- Myelosuppression (leukopenia, thrombocytopenia, anemia), neutropenic fever/infection, Coombs' positive hemolytic anemia, acute leukemia (generally when cisplatin given in combination with other leukemogenic agents).
- Gastrointestinal- Nausea, vomiting, diarrhea.
- Serum electrolyte disturbances- Hypomagnesemia, hypocalcemia, hyponatremia, hypokalemia, and hypophosphatemia.
- Hyperuricemia
- Neurotoxicity- Peripheral neuropathy, Lhermitte's sign, dorsal column myelopathy, autonomic neuropathy, loss of taste, seizures, leukoencephalopathy, reversible posterior leukoencephalopathy syndrome (RPLS), and muscle cramps.
- Ocular toxicity- Optic neuritis, papilledema, cerebral blindness, blurred vision, and altered color perception.
- Anaphylactic-like reactions- Facial edema, wheezing, tachycardia, and hypotension.
- Hepatotoxicity- Transient elevations of liver enzymes and bilirubin.
- Other events- Cardiac abnormalities, hiccups, elevated serum amylase, rash, alopecia, malaise, and dehydration.

OVERDOSAGE

- Acute overdosage may result in kidney failure, liver failure, deafness, ocular toxicity, significant myelosuppression, intractable nausea and vomiting and/or neuritis, and death.
- No proven antidotes have been established for cisplatin overdosage. Hemodialysis appears to have little effect. Management of overdosage should include general supportive measures to sustain the patient through any period of toxicity that may occur.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for CISPLATIN Injection.

AccuraSEE™ PACKAGING & LABELING

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Dexmedetomidine

Injection, USP

200 mcg per 2 mL | NDC 70860-605-03

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THE NEXT GENERATION OF PHARMACY INNOVATION

Dexmedetomidine

Injection, USP

200 mcg

NDC 70860-605-03
200 mcg per 2 mL

DESCRIPTION	Glass Vial
CONCENTRATION	100 mcg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes

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DOXOrubicin

HCl Injection, USP

50 mg per 25 mL | NDC 70860-208-25

200 mg per 100 mL | NDC 70860-208-51

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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR DOXORUBICIN HCl INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

DOXOrubicin

HCl Injection, USP

50 mg

NDC 70860-208-25
50 mg per 25 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

200 mg

NDC 70860-208-51
200 mg per 100 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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DOXORUBICIN HYDROCHLORIDE Injection

INDICATIONS AND USAGE

- Doxorubicin Hydrochloride (HCl) Injection is indicated as a component of multiagent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer.
- Doxorubicin HCl is indicated for the treatment of: acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin lymphoma, Non-Hodgkin lymphoma, metastatic breast cancer, metastatic Wilms' tumor, metastatic neuroblastoma, metastatic soft tissue sarcoma, metastatic bone sarcomas, metastatic ovarian carcinoma, metastatic transitional cell bladder carcinoma, metastatic thyroid carcinoma, metastatic gastric carcinoma, metastatic bronchogenic carcinoma.

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOMYOPATHY, SECONDARY MALIGNANCIES, EXTRAVASATION AND TISSUE NECROSIS, and SEVERE MYELOSUPPRESSION

- **Cardiomyopathy: Myocardial damage, including acute left ventricular failure can occur with doxorubicin HCl. The risk of cardiomyopathy is proportional to the cumulative exposure with incidence rates from 1% to 20% for cumulative doses ranging from 300 mg/m² to 500 mg/m² when doxorubicin HCl is administered every 3 weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess LVEF before and regularly during and after treatment with doxorubicin HCl.**
- **Secondary Malignancies: Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including doxorubicin HCl.**
- **Extravasation and Tissue Necrosis: Extravasation of doxorubicin HCl can result in severe local tissue injury and necrosis requiring wide excision of the affected area and skin grafting. Immediately terminate the drug and apply ice to the affected area.**
- **Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur.**

CONTRAINDICATIONS

- Doxorubicin HCl is contraindicated in patients with severe myocardial insufficiency.
- Doxorubicin HCl is contraindicated in patients with recent (occurring within the past 4 to 6 weeks) myocardial infarction.
- Doxorubicin HCl is contraindicated in patients with severe persistent drug-induced myelosuppression.
- Doxorubicin HCl is contraindicated in patients with severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin level greater than 5 mg/dL).
- Doxorubicin HCl is contraindicated in patients with severe hypersensitivity reaction to doxorubicin HCl including anaphylaxis.

WARNINGS AND PRECAUTIONS

- Doxorubicin HCl can result in myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy is generally proportional to the cumulative exposure. Include prior doses of other anthracyclines or anthracenediones in calculations of total cumulative dosage for doxorubicin HCl. Cardiomyopathy may develop during treatment or up to several years after completion of treatment and can include decrease in left ventricular ejection fraction (LVEF) and signs and symptoms of congestive heart failure (CHF). There is an additive or potentially synergistic increase in the risk of cardiomyopathy in patients who have received radiotherapy to the mediastinum or concomitant therapy with other known cardiotoxic agents such as cyclophosphamide and trastuzumab.
- Pericarditis and myocarditis have been reported during or following doxorubicin HCl treatment. Assess left ventricular function prior to initiation of doxorubicin HCl, during treatment to detect acute changes, and after treatment to detect delayed cardiotoxicity. Consider the use of dexrazoxane to reduce the incidence and severity of cardiomyopathy due to doxorubicin HCl administration in patients who have received a cumulative doxorubicin HCl dose of 300 mg/m² and who will continue to receive doxorubicin HCl.
- Doxorubicin HCl can result in arrhythmias, including life-threatening arrhythmias, during or within a few hours after doxorubicin HCl administration and at any time point during treatment.
- The risk of developing secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) is increased following treatment with doxorubicin HCl.
- Extravasation of doxorubicin HCl can result in severe local tissue injury manifesting as blistering, ulceration, and necrosis requiring wide excision of the affected area and skin grafting. When given via a peripheral venous line, infuse doxorubicin over 10 minutes or less to minimize the risk of thrombosis or perivenous extravasation. If extravasation is suspected, apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days. If appropriate, administer dexrazoxane at the site of extravasation as soon as possible and within the first 6 hours after extravasation.
- Doxorubicin HCl can cause myelosuppression. Obtain baseline assessment of blood counts and carefully monitor patients during treatment for possible clinical complications due to myelosuppression.
- The clearance of doxorubicin is decreased in patients with elevated serum bilirubin with an increased risk of toxicity. Reduce the dose of doxorubicin HCl in patients with serum bilirubin levels of 1.2 to 5.0 mg/dL. Obtain liver tests including SGOT, SGPT, alkaline phosphatase, and bilirubin prior to and during doxorubicin HCl therapy.
- Doxorubicin HCl may induce tumor lysis syndrome in patients with rapidly growing tumors. Evaluate blood uric acid levels, potassium, calcium, phosphate, and creatinine after initial treatment. Hydration, urine alkalinization, and prophylaxis with allopurinol to prevent hyperuricemia may minimize potential complications of tumor lysis syndrome.
- Doxorubicin HCl can increase radiation-induced toxicity to the myocardium, mucosa, skin, and liver. Radiation recall, including but not limited to cutaneous and pulmonary toxicity, can occur in patients who receive doxorubicin HCl after prior radiation therapy.
- Doxorubicin HCl can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus. Advise female patients of reproductive potential to use highly effective contraception during treatment with doxorubicin HCl and for 6 months after treatment. Advise patients to contact their healthcare provider if they become pregnant, or if pregnancy is suspected, while taking doxorubicin HCl.
- Doxorubicin HCl may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Males with female sexual partners of reproductive potential should use effective contraception during and for 6 months after treatment
- Because of the potential for serious adverse reactions in nursing infants from doxorubicin HCl, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
- In females of reproductive potential, doxorubicin HCl may cause infertility and result in amenorrhea. Premature menopause can occur. Recovery of menses and ovulation is related to age at treatment.
- In males, doxorubicin HCl may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men. This may occur several years after the end of therapy.

ADVERSE REACTIONS

- The most common (>10%) adverse drug reactions are alopecia, nausea, and vomiting.

OVERDOSAGE

- Few cases of overdose have been described. Acute overdosage with doxorubicin enhances the toxic effect of mucositis, leukopenia and thrombocytopenia. Treatment of acute overdosage consists of treatment of the severely myelosuppressed patient with hospitalization, antimicrobials, platelet transfusions and symptomatic treatment of mucositis. Use of hemopoietic growth factor (G-CSF, GM-CSF) may be considered.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for DOXORUBICIN HYDROCHLORIDE Injection.

Etomidate

Injection, USP

20 mg per 10 mL | NDC 70860-652-10

40 mg per 20 mL | NDC 70860-652-20

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THE NEXT GENERATION OF PHARMACY INNOVATION

Etomidate

Injection, USP

20 mg

NDC 70860-652-10
20 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

40 mg

NDC 70860-652-20
40 mg per 20 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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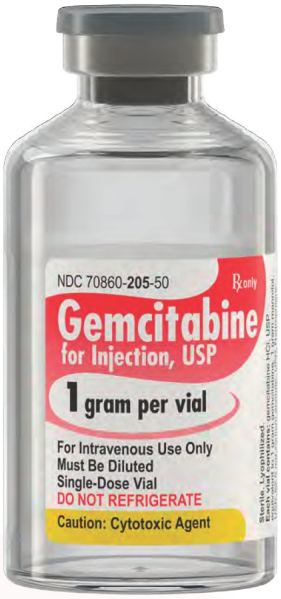
Gemcitabine
for Injection, USP

1 gram per vial | NDC 70860-205-50



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THE NEXT GENERATION OF PHARMACY INNOVATION

Gemcitabine

for Injection, USP

1 g

NDC 70860-205-50

1 gram per vial

DESCRIPTION	Glass Vial
CONCENTRATION	1 gram per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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Ketorolac
Tromethamine Injection, USP

15 mg per mL	|	NDC 70860-700-02
30 mg per mL	|	NDC 70860-701-03
60 mg per 2 mL	|	NDC 70860-701-04

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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR KETOROLAC TROMETHAMINE INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

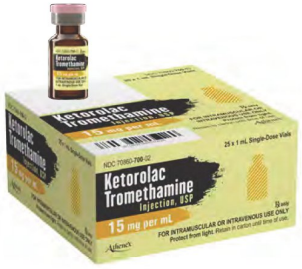
Ketorolac

Tromethamine Injection, USP

15 mg

NDC 70860-700-02
15 mg per mL

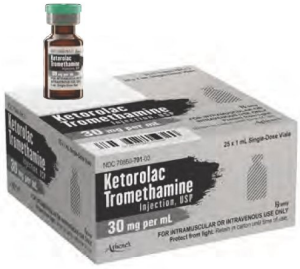
DESCRIPTION	Glass Vial
CONCENTRATION	15 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes



30 mg

NDC 70860-701-03
30 mg per mL

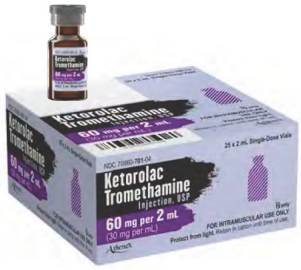
DESCRIPTION	Glass Vial
CONCENTRATION	30 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes



60 mg

NDC 70860-701-04
60 mg per 2 mL

DESCRIPTION	Glass Vial
CONCENTRATION	30 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes



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KETOROLAC TROMETHAMINE Injection, USP

INDICATIONS AND USAGE

- Ketorolac tromethamine is indicated for the short-term (<5 days) management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting.
- Therapy should always be initiated with IV or IM dosing of ketorolac tromethamine, and oral ketorolac tromethamine is to be used only as continuation treatment, if necessary.
- Patients should be switched to alternative analgesics as soon as possible, but ketorolac tromethamine therapy is not to exceed 5 days.

IMPORTANT SAFETY INFORMATION

WARNINGS

Ketorolac tromethamine, a nonsteroidal anti-inflammatory drug (NSAID), is indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level. Oral ketorolac tromethamine is indicated only as continuation treatment following IV or IM dosing of ketorolac tromethamine, if necessary. The total combined duration of use of oral ketorolac tromethamine and ketorolac tromethamine injection should not exceed 5 days.

Ketorolac tromethamine is not indicated for use in pediatric patients and it is NOT indicated for minor or chronic painful conditions. Increasing the dose of ketorolac tromethamine beyond the label recommendations will not provide better efficacy but will increase the risk of developing serious adverse events.

GASTROINTESTINAL RISK

- Ketorolac tromethamine can cause peptic ulcers, gastrointestinal bleeding and/or perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Therefore, ketorolac tromethamine is CONTRAINDICATED in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation, and in patients with a history of peptic ulcer disease or gastrointestinal bleeding. Elderly patients are at greater risk for serious gastrointestinal events (see **WARNINGS**).

CARDIOVASCULAR THROMBOTIC EVENTS

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use (see **WARNINGS** and **PRECAUTIONS**).
- Ketorolac Tromethamine Injection, USP is CONTRAINDICATED in the setting of coronary artery bypass graft (CABG) surgery (see **CONTRAINDICATIONS** and **WARNINGS**).

RENAL RISK

- Ketorolac tromethamine is CONTRAINDICATED in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion (see **WARNINGS**).

RISK OF BLEEDING

- Ketorolac tromethamine inhibits platelet function and is, therefore, CONTRAINDICATED in patients with suspected or confirmed cerebrovascular bleeding, patients with hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding (see **WARNINGS** and **PRECAUTIONS**).

Ketorolac tromethamine is CONTRAINDICATED as prophylactic analgesic before any major surgery.

HYPERSENSITIVITY

- Hypersensitivity reactions, ranging from bronchospasm to anaphylactic shock, have occurred and appropriate counteractive measures must be available when administering the first dose of ketorolac tromethamine injection (see **CONTRAINDICATIONS** and **WARNINGS**). Ketorolac tromethamine is CONTRAINDICATED in patients with previously demonstrated hypersensitivity to ketorolac tromethamine or allergic manifestations to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).

INTRATHECAL OR EPIDURAL ADMINISTRATION

- Ketorolac tromethamine is CONTRAINDICATED for intrathecal or epidural administration due to its alcohol content.

RISK DURING LABOR AND DELIVERY

- The use of ketorolac tromethamine In labor and delivery is CONTRAINDICATED because it may adversely affect fetal circulation and inhibit uterine contractions.

CONCOMITANT USE WITH NSAIOs

- Ketorolac tromethamine is CONTRAINDICATED in patients currently receiving aspirin or NSAIDs because of the cumulative risk of inducing serious NSAID-related side effects.

SPECIAL POPULATIONS

- Dosage should be adjusted for patients 65 years or older, for patients under 50 kg (110 lbs.) of body weight (see **DOSAGE AND ADMINISTRATION**) and for patients with moderately elevated serum creatinine (see **WARNINGS**). Doses of ketorolac tromethamine injection are not to exceed 60 mg (total dose per day) in these patients.

DOSAGE AND ADMINISTRATION

Ketorolac Tromethamine Tablets

- Ketorolac tromethamine tablets are indicated only as continuation therapy to ketorolac tromethamine injection, and the combined duration of use of ketorolac tromethamine injection and ketorolac tromethamine tablets is not to exceed 5 (five) days, because of the increased risk of serious adverse events.
- The recommended total daily dose of ketorolac tromethamine tablets (maximum 40 mg) is significantly lower than for ketorolac tromethamine injection (maximum 120 mg) (see **DOSAGE AND ADMINISTRATION**).

CONTRAINDICATIONS

- Ketorolac tromethamine is contraindicated in patients with previously demonstrated hypersensitivity to ketorolac tromethamine.
- Ketorolac tromethamine is contraindicated in patients with active peptic ulcer disease, in patients with recent gastrointestinal bleeding or perforation and in patients with a history of peptic ulcer disease or gastrointestinal bleeding.
- Ketorolac tromethamine should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.
- Ketorolac tromethamine is contraindicated as prophylactic analgesic before any major surgery.
- Ketorolac tromethamine is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- Ketorolac tromethamine is contraindicated in patients with advanced renal impairment or in patients at risk for renal failure due to volume depletion.
- Ketorolac tromethamine is contraindicated in labor and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect fetal circulation and inhibit uterine musculature, thus increasing the risk of uterine hemorrhage.
- Ketorolac tromethamine inhibits platelet function and is, therefore, contraindicated in patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding.
- Ketorolac tromethamine is contraindicated in patients currently receiving aspirin or NSAIDs because of the cumulative risks of inducing serious NSAID-related adverse events.
- The concomitant use of ketorolac tromethamine and probenecid is contraindicated.
- The concomitant use of ketorolac tromethamine and pentoxifylline is contraindicated
- Ketorolac tromethamine injection is contraindicated for neuraxial (epidural or intrathecal) administration due to its alcohol content.

WARNINGS

- The total combinedduration of use of oral ketorolac tromethamine and IV or IM dosing of ketorolac tromethamine is not to exceed 5 days in adults. Ketorolac tromethamine is not indicated for use in pediatric patients.
- Ketorolac tromethamine is contraindicated in patients with previously documented peptic ulcers and/or gastrointestinal (GI) bleeding.
- To minimize the potential risk for an adverse GI event, the lowest effective dose should be used for the shortest possible duration .

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- Use of ketorolac tromethamine In patients who have coagulati on disor ders should be undertaken very cautious ly, and those patients should be carefully monitored .
- In postmarketing experience, postoperative hematomas and other signs of wound bleeding have been reported in association with the peri-operative use of IV or IM dosing of ketorolac tromethamine. Therefore, peri-operative use of ketorolac tromethamine should be avoided and postoperative use be undertaken with caution when hemostasis is critical.
- Ketorolac t romethami ne should be used with caution in patients with impaired renal function. There have been reports of acute renal failure, interstitial nephritis, and nephrotic syndrome.
- Anaphylactoid reactions may occur in patients without known prior exposure to ketorolac tromethamine. Ketorolac tromethamine should not be given to patients with the aspirin t riad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Emergency help should be sought in cases where an anaphylactoid reaction occurs.
- Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction (MI) an d stroke, which can be fatal. To minimize the potential risk for an adverse CV event in NSAID-treated patients, use the lowest effective dose for the shortest duration possible.
- Avoid the use of Ketorolac Tromethamine Injection, USP in patients with a recent MI unless the benefits are expected to out weigh the risk of recurrent CV thrombotic events. If Ketorolac Tromethamine Injection, USP is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.
- NSAIDs, including ketorolac tromethamine, can lead to onset of new hypertension or worsening of pre-existing hypert ension, either of which may contribute to the increased incidence of CV events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAI Ds. NSAIOs, including ketorolac tromethamine, should be used with caution in patients with hypertension. Blood pressure (BP) should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.
- Fluid retention and edema have been observed in some patients treated with NSAIOs. Avoid the use of Ketorolac Tromethamine Injection, USP in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If Ketorolac Tromethamine Injection, USP is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.
- NSAIDs, including ketorolac tromethamine, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.
- In late pregnancy, as with other NSAIDs, ketorolac tromethamine should be avoided because it may cause premature closure of the ductus arteriosus.

PRECAUTIONS

- Ketorolac tromethamine cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency.
- Ketorolac tromethamine should be used with caution in patients with impaired hepatic function or a history of liver disease. Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs including ketorolac tromethamine.
- Anemia is sometimes seen in patients receiving NSAIDs, including ketorolac tromethamine. Patients receiving ketorolac tromethamine who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants, should be carefully monitored.
- Since cross reactivity, including bronchospasm, between aspirin and other nonsteroidal anti-inflammatory drugs has been reported in such aspirin-sensitive patients, ketorolac tromethamine should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with pre-existing asthma.
- Ketorolac tromethamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- The use of ketorolac tromethamine is contraindicated in labor and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage.
- The use of ketorolac tromethamine, as with any drug known to inhibit cyclooxygenase/ prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive.
- Exercise caution when ketorolac is administered to a nursing woman.
- Ketorolac tromethamine is not indicated for use in pediatric patients. The safety and effectiveness of ketorolac tromethamine in pediatric patients below the age of 17 have not been established.
- Extreme caution and reduced dosages and careful clinical monitoring must be used when treating the elderly with ketorolac tromethamine .

ADVERSE REACTIONS

- Adverse reaction rates increase with higher doses of ketorolac tromethamine. Practitioners should be alert for the severe complications of treatment with ketorolac tromethamine, such as GIulceration, bleeding and perforation, postoperative bleeding, acute renal failure, anaphylactic and anaphylactoid reactions and liver failure.
- The most frequently reported adverse experiences in approximately 1% to 10% of patients taking ketorolac tromethamine or other NSAIDs in clinical trials are nausea, headaches, abdominal pain, vomiting, flatulence, gross GI bleeding/perforation, stomatltis, constipation/ diarrhea, heartburn, dyspepsia and GI ulcers (gastroduodenal). Other adverse experiences are abnormal renal function, drowsiness, injection site pain, rash, anemia, edema, hypertension, pruritus, tinnitus, dizziness, elevated liver enzymes, increased bleeding tlp,e, and sweating.

OVERDOSAGE

- Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- Patients should be managed by symptomatic and supportive care following a NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 g to 100 g in adult s, 1 g/kg to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large oral overdose (5 to 10 times the usual dose).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch.
Or call 1-800-FDA-1088.

Please see full prescribing information for KETOROLAC TROMETHAMINE Injection, USP.

Levetiracetam
in Sodium Chloride Injection

500 mg per 100 mL	0.82% SODIUM CHLORIDE	NDC 70860-602-82
1,000 mg per 100 mL	0.75% SODIUM CHLORIDE	NDC 70860-603-82
1,500 mg per 100 mL	0.54% SODIUM CHLORIDE	NDC 70860-604-82

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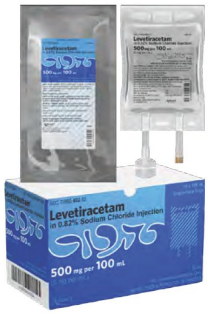
THE NEXT GENERATION OF PHARMACY INNOVATION

Levetiracetam
in Sodium Chloride Injection

500 mg

NDC 70860-602-82
500 mg per 100 mL

DILUENT	0.82% Sodium Chloride
CONCENTRATION	5 mg per mL
DESCRIPTION	Premix bag
UNIT OF SALE	10 bags
BAR CODED	Yes



1,000 mg

NDC 70860-603-82
1,000 mg per 100 mL

DILUENT	0.75% Sodium Chloride
CONCENTRATION	10 mg per mL
DESCRIPTION	Premix bag
UNIT OF SALE	10 bags
BAR CODED	Yes

1,500 mg

NDC 70860-604-82
1,500 mg per 100 mL

DILUENT	0.54% Sodium Chloride
CONCENTRATION	15 mg per mL
DESCRIPTION	Premix bag
UNIT OF SALE	10 bags
BAR CODED	Yes

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Levothyroxine
Sodium for Injection

100 mcg per vial	|	NDC 70860-451-10
200 mcg per vial	|	NDC 70860-452-10
500 mcg per vial	|	NDC 70860-453-10

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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR LEVOTHYROXINE FOR INJECTION, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Levothyroxine

Sodium for Injection

100 mcg

NDC 70860-451-10

100 mcg per vial

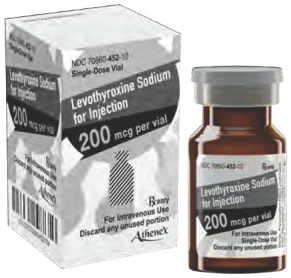
DESCRIPTION	Glass Vial
CONCENTRATION	100 mcg per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

200 mcg

NDC 70860-452-10

200 mcg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	200 mcg per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes



500 mcg

NDC 70860-453-10

500 mcg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	500 mcg per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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LEVOTHYROXINE SODIUM for Injection

INDICATIONS AND USAGE

- Levothyroxine Sodium is indicated for the treatment of myxedema coma.
- The relative bioavailability of this drug has not been established. Use caution when converting patients from oral to intravenous levothyroxine.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS
THYROID HORMONES, INCLUDING LEVOTHYROXINE SODIUM FOR INJECTION, SHOULD NOT BE USED FOR THE TREATMENT OF OBESITY OR FOR WEIGHT LOSS. LARGER DOSES MAY PRODUCE SERIOUS OR EVEN LIFE-THREATENING MANIFESTATIONS OF TOXICITY

CONTRAINDICATIONS

- None

WARNINGS AND PRECAUTIONS

- Excessive bolus doses of Levothyroxine Sodium for Injection (> 500 mcg) are associated with cardiac complications, particularly in the elderly and in patients with an underlying cardiac condition. Initiate therapy with doses at the lower end of the recommended range. Close observation of the patient following the administration of Levothyroxine Sodium for Injection is advised.
- There may be a need for concomitant glucocorticoids and monitoring for other diseases in patients with endocrine disorders. Occasionally, chronic autoimmune thyroiditis, which can lead to myxedema coma, may occur in association with other autoimmune disorders such as adrenal insufficiency, pernicious anemia, and insulin dependent diabetes mellitus. Patients should be treated with replacement glucocorticoids prior to initiation of treatment with Levothyroxine Sodium for Injection, until adrenal function has been adequately assessed. Failure to do so may precipitate an acute adrenal crisis when thyroid hormone therapy is initiated, due to increased metabolic clearance of glucocorticoids by thyroid hormone. With initiation of Levothyroxine Sodium for Injection, patients with myxedema coma should also be monitored for previously undiagnosed diabetes insipidus.
- Thyroid hormones, including Levothyroxine Sodium for Injection, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss.
- In late pregnancy, as with other NSAIDs, ketorolac tromethamine should be avoided because it may cause premature closure of the ductus arteriosus.

ADVERSE REACTIONS

- Excessive doses of levothyroxine can predispose to signs and symptoms compatible with hyperthyroidism. The signs and symptoms of thyrotoxicosis include, but are not limited to: exophthalmic goiter, weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, angina pectoris, tremors, insomnia, heat intolerance, fever, and menstrual irregularities.

OVERDOSAGE

- Levothyroxine Sodium for Injection should be reduced in dose or temporarily discontinued if signs or symptoms of overdosage occur. To obtain up-to-date information about the treatment of overdose, a good resource is the certified Regional Poison Control Center. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in the patient. In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's medical status.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch.
Or call 1-800-FDA-1088.

Please see full prescribing information for LEVOTHYROXINE SODIUM for Injection.

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Melphalan

Hydrochloride for Injection

50 mg per vial
with 10 mL Diluent | NDC 70860-214-61

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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR MELPHALAN HYDROCHLORIDE FOR INJECTION ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Melphalan

Hydrochloride for Injection

50 mg	NDC 70860-214-61 50 mg per vial	10 mL	10 mL Diluent
DESCRIPTION	Glass Vial	DESCRIPTION	Glass Vial
CONCENTRATION	50 mg per vial	FILL VOLUME	10 mL
CLOSURE	20 mm	CLOSURE	20 mm
UNIT OF SALE		1 Kit	
BAR CODED	Yes	BAR CODED	Yes

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MELPHALAN Hydrochloride for Injection

INDICATIONS AND USAGE

- Melphalan Hydrochloride for Injection is indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

IMPORTANT SAFETY INFORMATION

WARNING

MELPHALAN SHOULD BE ADMINISTERED UNDER THE SUPERVISION OF A QUALIFIED PHYSICIAN EXPERIENCED IN THE USE OF CANCER CHEMOTHERAPEUTIC AGENTS. SEVERE BONE MARROW SUPPRESSION WITH RESULTING INFECTION OR BLEEDING MAY OCCUR. CONTROLLED TRIALS COMPARING INTRAVENOUS (IV) TO ORAL MELPHALAN HAVE SHOWN MORE MYELOSUPPRESSION WITH THE IV FORMULATION. HYPERSENSITIVITY REACTIONS, INCLUDING ANAPHYLAXIS, HAVE OCCURRED IN APPROXIMATELY 2% OF PATIENTS WHO RECEIVED THE IV FORMULATION. MELPHALAN IS LEUKEMOGENIC IN HUMANS. MELPHALAN PRODUCES CHROMOSOMAL ABERRATIONS *IN VITRO* AND *IN VIVO* AND, THEREFORE, SHOULD BE CONSIDERED POTENTIALLY MUTAGENIC IN HUMANS.

CONTRAINDICATIONS

- Melphalan should not be used in patients whose disease has demonstrated prior resistance to this agent. Patients who have demonstrated hypersensitivity to melphalan should not be given the drug.

WARNINGS and PRECAUTIONS

- **Extravasation:** Melphalan hydrochloride for injection may cause local tissue damage should extravasation occur, and consequently it should not be administered by direct injection into a peripheral vein. It is recommended that melphalan hydrochloride for injection be administered by injecting slowly into a fast-running IV infusion via an injection port, or via a central venous line.
- **Melphalan hydrochloride for injection should be administered in carefully adjusted dosage by or under the supervision of experienced physicians who are familiar with the drug's actions and the possible complications of its use.**
- **Bone Marrow Suppression:** Bone marrow suppression is the most significant toxicity associated with melphalan hydrochloride for injection in most patients. Hematologic tests (platelet count, hemoglobin, white blood cell count, and differential) should be performed at the start of therapy and prior to each subsequent dose. Thrombocytopenia or leukopenia are indications to withhold further therapy until the blood counts have sufficiently recovered. Dose adjustments should be considered on the basis of blood counts at the nadir and day of treatment. Use with extreme caution in patients whose bone marrow reserve may have been compromised by prior irradiation or chemotherapy or whose marrow function is recovering from previous cytotoxic therapy.
- **Hypersensitivity Reactions:** Hypersensitivity reactions including anaphylaxis have occurred in approximately 2% of patients who received the IV formulation of melphalan. These reactions usually occur after multiple courses of treatment. Treatment is symptomatic. The infusion should be terminated immediately, followed by the administration of volume expanders, pressor agents, corticosteroids, or antihistamines at the discretion of the physician. If a hypersensitivity reaction occurs, IV or oral melphalan should not be readministered since hypersensitivity reactions have also been reported with oral melphalan.
- **Secondary Malignancies:** Secondary malignancies, including acute nonlymphocytic leukemia, myeloproliferative syndrome, and carcinoma, have been reported in patients with cancer treated with alkylating agents (including melphalan). Precise quantitation of the risk of acute leukemia, myeloproliferative syndrome, or carcinoma is not possible. Published reports of leukemia in patients who have received melphalan (and other alkylating agents) suggest that the risk of leukemogenesis increases with chronicity of treatment and with cumulative dose, although this does not mean that there is a cumulative dose below which there is no risk of the induction of secondary malignancy. The potential benefits from melphalan therapy must be weighed on an individual basis against the possible risk of the induction of a second malignancy.
- **Genetic Effect:** Melphalan has been shown to cause chromatid or chromosome damage in humans.
- **Use in Specific Populations:**
  - Melphalan causes suppression of ovarian function in premenopausal women, resulting in amenorrhea in a significant number of patients. Reversible and irreversible testicular suppression have also been reported.
  - Melphalan is a pregnancy category D agent and may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant.
  - It is not known whether this drug is excreted in human milk. IV melphalan should not be given to nursing mothers.
  - Dose reduction should be considered in patients with renal insufficiency receiving IV melphalan.
  - Administration of live vaccines to immunocompromised patients should be avoided.
- **Drug Interactions:** The development of severe renal failure has been reported in patients treated with a single dose of IV melphalan followed by standard oral doses of cyclosporine. Cisplatin may affect melphalan kinetics by inducing renal dysfunction and subsequently altering melphalan clearance. IV melphalan may also reduce the threshold for BCNU lung toxicity. When nalidixic acid and IV melphalan are given simultaneously, the incidence of severe hemorrhagic necrotic enterocolitis has been reported to increase in pediatric patients.

ADVERSE REACTIONS

- The most common side effect is bone marrow suppression leading to leukopenia, thrombocytopenia, and anemia. Blood count nadirs usually occur 2 to 3 weeks after treatment.
- Gastrointestinal disturbances such as nausea and vomiting, diarrhea, and oral ulceration occur infrequently. Hepatic disorders ranging from abnormal liver function tests to clinical manifestations such as hepatitis and jaundice have been reported. Hepatic veno-occlusive disease has been reported.
- Acute hypersensitivity reactions can occur in patients receiving melphalan hydrochloride for injection, characterized by urticaria, pruritus, edema, skin rashes, and in some patients, tachycardia, bronchospasm, dyspnea, hypotension, and rarely, cardiac arrest. Patients may respond to antihistamine and corticosteroid therapy.
- Other reported adverse reactions include skin hypersensitivity, skin ulceration at injection site, skin necrosis rarely requiring skin grafting, maculopapular rashes, vasculitis, alopecia, hemolytic anemia, allergic reaction, pulmonary fibrosis (including fatal outcomes), and interstitial pneumonitis. Temporary significant elevation of the blood urea has been seen in the early stages of therapy in patients with renal damage. Subjective and transient sensation of warmth or tingling can occur.

OVERDOSAGE

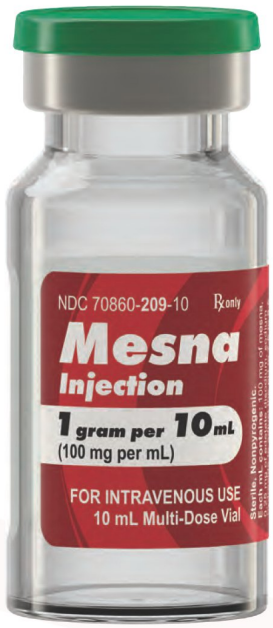
- The principal toxic effect of overdosage with melphalan is bone marrow suppression. Hematologic parameters should be closely followed for 3 to 6 weeks. Administration of autologous bone marrow or hematopoietic growth factors may shorten the period of pancytopenia.
- General supportive measures together with appropriate blood transfusions and antibiotics should be instituted as deemed necessary.
- Melphalan is not removed from plasma to any significant degree by hemodialysis or hemoperfusion.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for MELPHALAN Hydrochloride for Injection.

Mesna
Injection

1 gram per 10 mL | NDC 70860-209-10 | 1 vial



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THE NEXT GENERATION OF PHARMACY INNOVATION

Mesna

Injection

1 g

NDC 70860-209-10
1 gram per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	100 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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Methocarbamol

Injection, USP

1,000 mg per 10 mL | NDC 70860-653-10

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THE NEXT GENERATION OF PHARMACY INNOVATION

Methocarbamol

Injection, USP

1,000 mg

NDC 70860-653-10
1,000 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	100 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes

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Metoprolol Tartrate

Injection, USP

5 mg per 5 mL | NDC 70860-300-05

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THE NEXT GENERATION OF PHARMACY INNOVATION

Metoprolol Tartrate

Injection, USP

5 mg

NDC 70860-300-05
5 mg per 5 mL

DESCRIPTION	Glass Vial
CONCENTRATION	1 mg per mL
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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Midazolam

Injection, USP

2 mg per 2 mL	NDC 70860-600-02
25 mg per 5 mL	NDC 70860-601-05
50 mg per 10 mL	NDC 70860-601-10

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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR MIDAZOLAM INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Midazolam

Injection, USP

2 mg — NDC 70860-600-02 — 2 mg per 2 mL

DESCRIPTION	Glass Vial
CONCENTRATION	1 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes

25 mg — NDC 70860-601-05 — 25 mg per 5 mL

DESCRIPTION	Glass Vial
CONCENTRATION	5 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

50 mg — NDC 70860-601-10 — 50 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	5 mg per mL
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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Midazolam Injection, USP

INDICATIONS AND USAGE

Midazolam Injection, USP indications:

- Intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia.
- Intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants.
- Intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotic premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period of time. Intravenous midazolam can also be used as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia).
- Continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

IMPORTANT SAFETY INFORMATION

WARNINGS

Personnel and Equipment for Monitoring and Resuscitation

Adults and Pediatrics: **Intravenous midazolam hydrochloride has been associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings. In some cases, where this was not recognized promptly and treated effectively, death or hypoxic encephalopathy has resulted. Intravenous mIdazolam hydrochloride should be used only in hospital or ambulatory care settings, including physicians' and dental offices, that provide for continuous monitoring of respiratory and cardiac function, e.g., pulse oximetry. Immediate availability of resuscitative drugs and age- and size-appropriate equipment for bag/valve/mask ventilation and Intubation, and personnel trained in their use and skilled in airway management should be assured (see WARNINGS). For deeply sedated pediatric patients, a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.**

Risks from Concomitant Use with Opioids

Concomitant use of benzodiazepines and opIoids may result in profound sedation, respiratory depression, coma, and death. Monitor patients for respiratory depression and sedation (see WARNINGS and PRECAUTIONS, Drug Interactions).

Individualization of Dosage

Midazolam hydrochloride must never be used without individualization of dosage. The initial Intravenous dose for sedation in adult patients may be as little as 1 mg, but should not exceed 2.5 mg in a normal healthy adult. Lower doses are necessary for older (over 60 years) or debilitated patients and In patients receiving concomitant narcotics or other central nervous system (CNS) depressants. The initial dose and all subsequent doses should always be titrated slow ly administer over at least Z minutes and allow an additional Z or more minutes to fully evaluate the sedative effect. The use of the 1 mg/ml formulation or dilution of the 1 mg/ml or 5 mg/ml formulation is recommended to facilitate slower injection. Doses of sedative medications in pediatric patients must be calculated on a mg/kg basis, and initial doses and all subsequent doses should always be titrated slowly. The Initial pediatric dose of midazolam for sedation/anxIolysis/amnesia is age, procedure, and route dependent (see DOSAGE AND ADMINISTRATION for complete dosing in formation).

Neonates: **Midazolam should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly with concomitant use of fentanyl (see DOSAGE AND ADMINISTRATION for complete information) .**

CONTRAINDICATIONS

- Injectable midazolam hydrochlor ide is contraindicated in patients with a known hypersensitivity to the drug. Benzodiazepines are contrain dicated in patients with acute narrow-angle glaucoma. Benzodiazepines may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Measurements of intraocular pressure in patients without eye disease show a moderate lowering following induction with midazolam hydrochloride; patients with glaucoma have not been studied.
- Midazolam hydrochloride mufti-dose vial, is not intended for intrathecal or epidural administration, and is contraindicated for use in premature infants, because the formulation contains benzyl alcohol as a preservative.

WARNINGS

- Prior to the Intravenous administration of midazolam hydrochloride in any dose, the immediate availability of oxygen, resuscitative drugs, age- and size-appropriate equipment for bag/valve/mask ventilation and intubation, and skilled personnel for the maintenance of a patent airway and support of ventilation should be ensured.
- Patients should be continuously monitored for early signs of hypoventilation, airway obstruction, or apnea with means readily available (e.g., pulse oximetry).
- The immediate availability of specific reversal agents (flumazenil) is highly recommended.
- Because intravenous midazolam can depress respiration, especially when used concomitant ly with opioid agonists and other sedatives, it should be titrated slowly when used for sedati on/anxiolysis/ amnesia.
- Concomitant use of benzodiazepines, including mIdazolam, and opioids may result in profound sedation, respiratory depression, coma, and deat h.
- Serious cardiorespiratory adverse events have occurred after administration of midazolam. These have included respiratory depression, airway obstruction, oxygen desaturation, apnea, respiratory arrest and/or cardiac arrest, sometimes resulting in death or permanent neurologic injury.
- Midazolam hydrochloride must never be used without individualization of dosage particularly when used with other medications capable of producing central nervous system depression.
- Reactions such as agitation, involuntary movements (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness have been reported in both adult and pediatric patients and may be due to inadequate or excessive dosing or improper administration of midazolam hydrochloride; however, consideration should be given to the possibility or cerebral hypoxia or true paradoxical reactions.
- Concomitant use of barbiturates, alcohol or other central nervous system depressants may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect. Narcotic premedication also depresses the ventilatory response to carbon dioxide stimulation.
- Higher risk adult and pediatric surgical patients, elderly pati nts, and debilitated adult and pediatric patients require lower dosages, whether or not concomitant sedating medications have been administered.
- Injectable midazolam should not be administered to adult or pediatric patients in shock or coma, or in acute alcohol intoxication with depression of vital signs. Particular care should be exercised in the use of intravenous midazolam in adult or pediatric patients with uncompensated acute illnesses, such as severe fluid or electrolyte disturbances.
- The safety and efficacy of midazolam following non-intravenous and non-intramuscular routes of administration have not been established. Midazolam hydrochloride should only be administered intramuscularly or intravenously. Extravasation should be avoided.
- It is recommended that no patient operate hazardous machinery or a motor vehicle until the effects of the drug, such as drowsiness, have subsided or until 1 full day after anesthesia and surgery, whichever is longer. For pediatric patients, particular care should be taken to assure safe ambulation.
- If this drug is used during pregnancy, the patient should be apprised of the potential hazard to the fetus, and is not recommended for obstetrical use.
- Rapid injection should be avoided in the neonatal population.
- The recommended dosage range of midazolam hydrochloride (multi-dose vial) for preterm and term infants includes benzyl alcohol well below that associated with toxicity; however, the amount of benzyl alcohol at which toxicity may occur is not known. If the patient requires more than the recommended dosages or other medications containing this preservative, the practitioner must consider the daily metabolic load of benzyl alcohol from these combined sources.
- Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

PRECAUTIONS

- Intravenous doses of midazolam hydrochloride should be decreased for elderly and for debilitated patient s. These patients will also probably take longer to recover completely after midazolam administration for the induction of anesthesia .
- Midazolam does not protect against the increase in intracranial pressure or against the heart rate rise and/or blood pressure rise associated with endotracheal intubation under light general anesthesia.
- Care must be taken to individualize and carefully titrate the dose of midazol am hydrochloride to the patient's underlying medical/surgical conditions, administer to the desired effect being certain to wait an adequate time for peak CNS effects of both midazolam hydrochloride and concomitant medications, and have the personnel and size appropriate equipment and facilities available for monitoring and intervention.
- Exercise caution when midazolam hydrochloride is administered to a nursing woman.

ADVERSE REACTIONS

- The primary adverse events associate with midazolam are related to central nervous system depression, cardiorespiratory events, and possible paradoxical reactions. These include decreased tidal volume/respiratory rate, apnea, dyspnea, shallow respirations, tachypnea, premature ventricular contractions, variations in blood pressure and pulse rate, involunt ary movements, hyperactivity and combativeness.
- Other adverse effects include, but are not limited to: headache, inje ction site reactions (tenderness, pain, redness, induration, phlebitis, warmth coldness at i njection site), hiccups, nausea, vomiting, coughing, drowsi ness, retrograde amnesia, hallucination, confusion, blurred vision, diplopia, nystagmus, and all ergic/anaphylactoid reactions (hives, rash pruritus).

OVERDOSAGE

- Treatment of injectable midazola m overdosage is the same as that followed for overdosage with other benzodiazepines. Respiration, pulse rat e and blood pressure should be monitored and general supportive measures should be employed. Attention should be given to the maintenance of a patent airway and support of ventil at io n, including administration of oxygen. An intravenous infusion should be started. Should hypotension develop, treatment may include intravenous fluid therapy, reposit ion i ng, jud icious use of vasopressors appropriate to the clinical si t uation, if in dicat ed, an d other appropria t e countermeasures. There is no information as to whether peri t oneal dialysis, forced diuresis or hemodialysis are of any value in the treatment of midazolam overdosage
- Flumazenil, a specific benzodiazepine-receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines and may be used in situations when an overdose with a benzo d iaze pine is known or suspected. Prior to the administration of flumazenil, necessary measures should be instituted to secure the airway, assure adequate ventilation, and establish adequate intravenous access. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for resedation, respiratory depression and other residual benzodiazepine effects for an appropriate period after treatment. flumazenil will only reverse benzodiazepine-induced effects but will not reverse the effects of other concomitant medications.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, Or call 1-800-FDA-1088.

Please see full prescribing information for MIDAZOLAM Injection, USP.

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Nafcillin
for Injection, USP

1 gram per vial		NDC 70860-116-26
2 gram per vial		NDC 70860-117-26
10 gram per vial		NDC 70860-119-99

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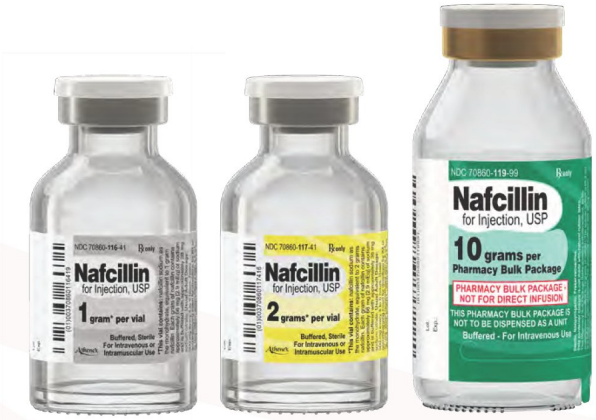


THE NEXT GENERATION OF PHARMACY INNOVATION

Nafcillin
for Injection, USP

1 g

NDC 70860-116-26
1 gram per vial

DESCRIPTION	Glass Vial
CONCENTRATION	1 gram per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

2 g

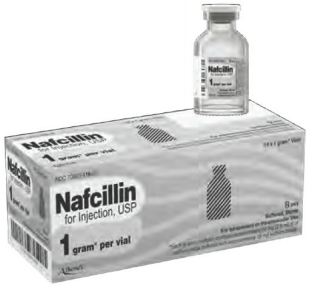
NDC 70860-117-26
2 gram per vial

DESCRIPTION	Glass Vial
CONCENTRATION	2 gram per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

10 g

NDC 70860-119-99
10 gram per vial

DESCRIPTION	Pharmacy Bulk Package
CONCENTRATION	10 gram per vial
CLOSURE	32 mm
UNIT OF SALE	1 vial
BAR CODED	Yes



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Ondansetron
Injection, USP

4 mg per 2 mL | NDC 70860-776-02

40 mg per 20 mL | NDC 70860-777-20

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THE NEXT GENERATION OF PHARMACY INNOVATION

Ondansetron

Injection, USP

4 mg

NDC 70860-776-02

4 mg per 2 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 vials
BAR CODED	Yes

40 mg

NDC 70860-777-20

40 mg per 20 mL

DESCRIPTION	Glass Vial
CONCENTRATION	2 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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Oxaliplatin
Injection, USP

50 mg per 10 mL | NDC 70860-201-10

100 mg per 20 mL | NDC 70860-201-20

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THE NEXT GENERATION OF PHARMACY INNOVATION

Oxaliplatin

Injection, USP

50 mg

NDC 70860-201-10

50 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	5 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

100 mg

NDC 70860-201-20

100 mg per 20 mL

DESCRIPTION	Glass Vial
CONCENTRATION	5 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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OXALIPLATIN Injection, USP

INDICATION AND USAGE

- Oxaliplatin Injection, USP used in combination with infusional 5-fluorouracil/leucovorin, is indicated for:
- adjuvant treatment of stage III colon cancer in patients who have undergone complete resection of the primary tumor.
- treatment of advanced colorectal cancer.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLACTIC REACTIONS

Anaphylactic reactions to Oxaliplatin Injection, USP have been reported, and may occur within minutes of Oxaliplatin Injection, USP administration. Epinephrine, corticosteroids, and antihistamines have been employed to alleviate symptoms of anaphylaxis *[see Warnings and Precautions]*.

CONTRAINDICATIONS

Oxaliplatin Injection, USP should not be administered to patients with a history of known allergy to Oxaliplatin Injection, USP or other platinum compound.

WARNINGS AND PRECAUTIONS

- Allergic Reactions: Monitor for development of rash, urticaria, erythema, pruritis, bronchospasm, and hypotension. Drug-related deaths associated with platinum compounds from anaphylaxis have been reported.
- Neuropathy: Reduce the dose or discontinue Oxaliplatin Injection, USP if necessary. An acute, reversible, primarily peripheral, sensory neuropathy that is of early onset, occurring within hours or one to two days of dosing, that resolves within 14 days, and that frequently recurs with further dosing. A persistent (>14 days), primarily peripheral, sensory neuropathy that is usually characterized by paresthesias, dysesthesias, hypoesthesias, but may also include deficits in proprioception that can interfere with daily activities.
- Severe Neutropenia: Grade 3 or 4 neutropenia occurred in 41 to 44% of patients with colorectal cancer treated with Oxaliplatin Injection, USP in combination with 5-flurouracil (5-FU) and leucovorin compared to 5% with 5-FU plus leucovorin alone. Sepsis, neutropenic sepsis and septic shock have been reported in patients treated with Oxaliplatin Injection, USP, including fatal outcomes. Delay Oxaliplatin Injection, USP until neutrophils are ff1.5 x 109/L. Withhold Oxaliplatin Injection, USP for sepsis or septic shock. Dose reduce Oxaliplatin Injection, USP after recovery from Grade 4 neutropenia or febrile neutropenia.
- Pulmonary Toxicity: May need to discontinue Oxaliplatin Injection, USP until interstitial lung disease or pulmonary fibrosis are excluded. Oxaliplatin Injection, USP has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal.
- Hepatotoxicity: Monitor liver function tests.
- Cardiovascular Toxicity: Oxaliplatin has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal. QT prolongation and ventricular arrhythmias including fatal Torsade de Pointes have been reported in postmarketing experiences following Oxaliplatin administration. ECG monitoring is recommended if therapy is initiated in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics, and electrolyte abnormalities. Correct hypokalemia or hypomagnesemia prior to initiating Oxaliplatin and monitor these electrolytes periodically during therapy. Avoid Oxaliplatin Injection, USP in patients with congenital long QT syndrome.
- Rhabdomyolysis, including fatal cases, has been reported in patients treated with Oxaliplatin. Discontinue Oxaliplatin if rhabdomyolysis occurs.
- Pregnancy. Fetal harm can occur when administered to a pregnant woman. Women should be apprised of the potential harm to the fetus.
- Recommended Laboratory Tests: Standard monitoring of the white blood cell count with differential, hemoglobin, platelet count, and blood chemistries (including ALT, AST, bilirubin and creatinine) is recommended before each Oxaliplatin Injection, USP cycle.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ff140%) were peripheral sensory neuropathy, neutropenia, thrombocytopenia, anemia, nausea, increase in transaminases and alkaline phosphatase, diarrhea, emesis, fatigue and stomatitis.
- Serious adverse reactions, including anaphylaxis and allergic reactions, neuropathy, severe neutropenia, pulmonary toxicities, hepatotoxicity, cardiovascular toxicities and rhabdomyolysis can occur.

OVERDOSAGE

- There is no known antidote for Oxaliplatin overdose. In addition thrombocytopenia, the anticipated complication of an oxaliplatin overdose include hypersensitivity reaction, myelosuppression, nausea, vomiting, diarrhea and neurotoxicity.
- Patients suspected of receiving an overdose should be monitored, and supportive treatment should be administered. The maximum dose of oxaliplatin that has been administered in a high infusion is 825 mg.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for OXALIPLATIN Injection, USP.

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Paclitaxel

Injection, USP

30 mg per 5 mL	NDC 70860-200-05
100 mg per 16.7 mL	NDC 70860-200-17
300 mg per 50 mL	NDC 70860-200-50

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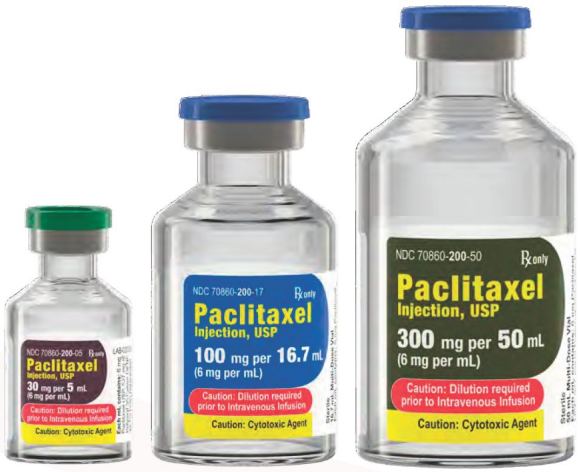

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR PACLITAXEL INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Paclitaxel

Injection, USP

30 mg — NDC 70860-200-05 — 30 mg per 5 mL

DESCRIPTION	Glass Vial
CONCENTRATION	6 mg per mL
CLOSURE	13 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

100 mg — NDC 70860-200-17 — 100 mg per 16.7 mL

DESCRIPTION	Glass Vial
CONCENTRATION	6 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

300 mg — NDC 70860-200-50 — 300 mg per 50 mL

DESCRIPTION	Glass Vial
CONCENTRATION	6 mg per mL
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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PACLITAXEL Injection, USP

INDICATIONS AND USAGE

- Paclitaxel Injection, USP is indicated as subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, paclitaxel is indicated in combination with cisplatin.
- Paclitaxel is indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.
- Paclitaxel Injection, USP is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Paclitaxel, in combination with cisplatin, is indicated for the first-line treatment of nonsmall cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.
- Paclitaxel is indicated for the second-line treatment of AIDS-related Kaposi's sarcoma.

IMPORTANT SAFETY INFORMATION

WARNING

Paclitaxel Injection, USP should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred in 2% to 4% of patients receiving paclitaxel in clinical trials. Fatal reactions have occurred in patients despite premedication. All patients should be pretreated with corticosteroids, diphenhydramine, and H2 antagonists (see DOSAGE AND ADMINISTRATION section). Patients who experience severe hypersensitivity reactions to paclitaxel should not be rechallenged with the drug.

Paclitaxel therapy should not be given to patients with solid tumors who have baseline neutrophil counts of less than 1,500 cells/mm3 and should not be given to patients with AIDS-related Kaposi's sarcoma if the baseline neutrophil count is less than 1,000 cells/mm3. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving paclitaxel.

CONTRAINDICATIONS

- Paclitaxel Injection, USP is contraindicated in patients who have a history of hypersensitivity reactions to paclitaxel or other drugs formulated in Polyoxyl 35 Castor Oil, NF
- Paclitaxel Injection, USP should not be used in patients with solid tumors who have baseline neutrophil counts of <1,500 cells/mm3 or in patients with AIDS-related Kaposi's sarcoma with baseline neutrophil counts of <1,000 cells/mm3.

WARNINGS

- Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred in 2% to 4% of patients receiving paclitaxel in clinical trials
- Fatal reactions have occurred in patients despite premedication. All patients should be pretreated with corticosteroids, diphenhydramine, and H2 antagonists
- Patients who experience severe hypersensitivity reactions to paclitaxel should not be rechallenged with the drug.
- Bone marrow suppression (primarily neutropenia) is dose-dependent and is the dose-limiting toxicity of Paclitaxel Injection. Frequent monitoring of blood counts should be instituted during paclitaxel treatment.
- Severe conduction abnormalities have been documented in <1% of patients during paclitaxel therapy and in some cases requiring pacemaker placement
- Paclitaxel can cause fetal harm when administered to a pregnant woman.

PRECAUTIONS

- Contact of the undiluted concentrate with plasticized polyvinyl chloride (PVC) equipment or devices used to prepare solutions for infusion is not recommended.
- Paclitaxel should be administered through an in-line filter with a microporous membrane not greater than 0.22 microns.
- The metabolism of paclitaxel is catalyzed by cytochrome P450 isoenzymes CYP2C8 and CYP3A4. In the absence of formal clinical drug interaction studies, caution should be exercised when administering paclitaxel concomitantly with known substrates or inhibitors of the cytochrome P450 isoenzymes CYP2C8 and CYP3A4.
- Paclitaxel therapy should not be administered to patients with baseline neutrophil counts of less than 1,500 cells/mm3.
- Patients with a history of severe hypersensitivity reactions to products containing Polyoxyl 35 Castor Oil, NF (e.g., cyclosporin for injection concentrate and teniposide for injection concentrate) should not be treated with paclitaxel.
- In order to avoid the occurrence of severe hypersensitivity reactions, all patients treated with paclitaxel should be premedicated with corticosteroids (such as dexamethasone), diphenhydramine and H2 antagonists (such as cimetidine or ranitidine).
- Hypotension, bradycardia, and hypertension have been observed during administration of Paclitaxel Injection, USP, but generally do not require treatment.
- Injection site reactions, including reactions secondary to extravasation, were usually mild and consisted of erythema, tenderness, skin discoloration, or swelling at the injection site.

ADVERSE REACTIONS

- Bone marrow suppression was the major dose-limiting toxicity of paclitaxel. Neutropenia, the most important hematologic toxicity, was dose and schedule dependent and was generally rapidly reversible.
- Other serious adverse events that occurred with use of paclitaxel were alopecia, anemia, arthralgia/myalgia, diarrhea, leukopenia, nausea/vomiting, peripheral neuropathy, thrombocytopenia, mucositis, hypersensitivity, renal impairment, hypotension.

OVERDOSAGE

- There is no known antidote for paclitaxel overdosage. The primary anticipated complications of overdosage would consist of bone marrow suppression, peripheral neurotoxicity, and mucositis. Overdoses in pediatric patients may be associated with acute ethanol toxicity

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for PACLITAXEL Injection, USP.

Penicillin G

Potassium for Injection, USP

5,000,000 units per vial | NDC 70860-126-20

20,000,000 units per vial | NDC 70860-127-51

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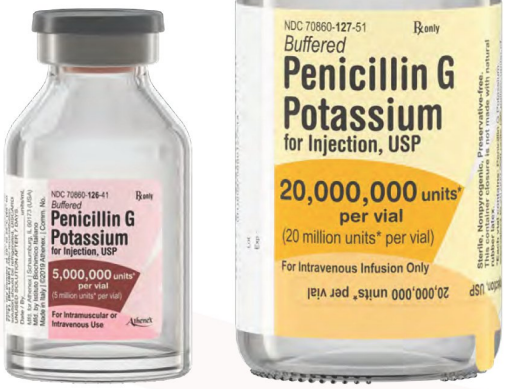

THE NEXT GENERATION OF PHARMACY INNOVATION

Penicillin G

Potassium for Injection, USP

NDC 70860-126-20
5,000,000 units per vial

DESCRIPTION	Glass Vial
CONCENTRATION	5,000,000 units per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

NDC 70860-127-51
20,000,000 units per vial

DESCRIPTION	Glass Vial
CONCENTRATION	20,000,000 units per vial
CLOSURE	32 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

• PRESERVATIVE-FREE • NOT MADE WITH NATURAL RUBBER LATEX • AP-RATED •

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Piperacillin and Tazobactam
for Injection

2.25 grams per vial	|	NDC 70860-120-20
3.375 grams per vial	|	NDC 70860-121-30
4.5 grams per vial	|	NDC 70860-122-50
40.5 grams per vial	|	NDC 70860-123-99

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THE NEXT GENERATION OF PHARMACY INNOVATION

Piperacillin and Tazobactam

for Injection

2.25 g — NDC 70860-120-20 — 2.25 grams per vial

DESCRIPTION	Glass Vial
CONCENTRATION	2.25 grams per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

3.375 g — NDC 70860-121-30 — 3.375 grams per vial

DESCRIPTION	Glass Vial
CONCENTRATION	3.375 grams per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

4.5 g — NDC 70860-122-50 — 4.5 grams per vial

DESCRIPTION	Glass Vial
CONCENTRATION	4.5 grams per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

40.5 g — NDC 70860-123-99 — 40.5 grams per vial

DESCRIPTION	Pharmacy Bulk Package
CONCENTRATION	40.5 grams per vial
CLOSURE	32 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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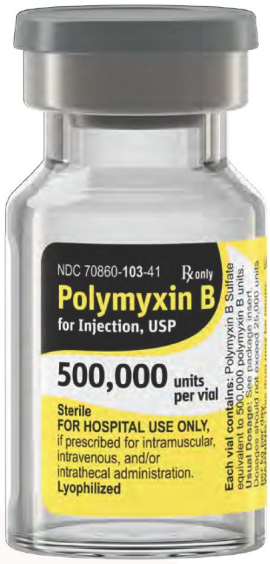
Polymyxin B
for Injection, USP

500,000 units per vial | NDC 70860-103-10



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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR POLYMYXIN B FOR INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Polymyxin B

for Injection, USP

NDC 70860-103-10
500,000 units per vial

DESCRIPTION	Glass Vial
CONCENTRATION	500,000 units per vial
CLOSURE	20 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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POLYMYXIN B for Injection, USP

INDICATION AND USAGE

- Polymyxin B sulfate is a drug of choice in the treatment of infections of the urinary tract, meninges, and bloodstream caused by susceptible strains of *Ps. aeruginosa.*
- It may also be used topically and subconjunctivally in the treatment of infections of the eye caused by susceptible strains of *Ps. aeruginosa.*
- It may be indicated in serious infections caused by susceptible strains of H. influenzae, specifically in meningeal infections, *Escherichia coli*, specifically in urinary tract infections, Aerobacter aerogenes , specifically in bacteremia and *Klebsiella pneumoniae*, specifically in bacteremia, when less potentially toxic drugs are ineffective or contraindicated.

IMPORTANT SAFETY INFORMATION

WARNING

CAUTION: WHEN THIS DRUG IS GIVEN INTRAMUSCULARLY AND/OR INTRATHECALLY, IT SHOULD BE GIVEN ONLY TO HOSPITALIZED PATIENTS, SO AS TO PROVIDE CONSTANT SUPERVISION BY A PHYSICIAN.

RENAL FUNCTION SHOULD BE CAREFULLY DETERMINED AND PATIENTS WITH RENAL DAMAGE AND NITROGEN RETENTION SHOULD HAVE REDUCED DOSAGE. PATIENTS WITH NEPHROTOXICITY DUE TO POLYMYXIN B SULFATE USUALLY SHOW ALBUMINURIA, CELLULAR CASTS, AND AZOTEMIA. DIMINISHING URINE OUTPUT AND A RISING BUN ARE INDICATIONS FOR DISCONTINUING THERAPY WITH THIS DRUG.

NEUROTOXIC REACTIONS MAY BE MANIFESTED BY IRRITABILITY, WEAKNESS, DROWSINESS, ATAXIA, PERIORAL PARESTHESIA, NUMBNESS OF THE EXTREMITIES, AND BLURRING OF VISION. THESE ARE USUALLY ASSOCIATED WITH HIGH SERUM LEVELS FOUND IN PATIENTS WITH IMPAIRED RENAL FUNCTION AND/OR NEPHROTOXICITY.

THE CONCURRENT OR SEQUENTIAL USE OF OTHER NEUROTOXIC AND/OR NEPHROTOXIC DRUGS WITH POLYMYXIN B SULFATE, PARTICULARLY BACITRACIN, STREPTOMYCIN, NEOMYCIN, KANAMYCIN, GENTAMICIN, TOBRAMYCIN, AMIKACIN, CEPHALORIDINE, PAROMOMYCIN, VIOMYCIN, AND COLISTIN SHOULD BE AVOIDED.

THE NEUROTOXICITY OF POLYMYXIN B SULFATE CAN RESULT IN RESPIRATORY PARALYSIS FROM NEUROMUSCULAR BLOCKADE, ESPECIALLY WHEN THE DRUG IS GIVEN SOON AFTER ANESTHESIA AND/OR MUSCLE RELAXANTS.

USAGE IN PREGNANCY: THE SAFETY OF THIS DRUG IN HUMAN PREGNANCY HAS NOT BEEN ESTABLISHED.

CONTRAINDICATIONS

Polymyxin B for Injection, USP is contraindicated in persons with a prior history of hypersensitivity reactions to polymyxins.

WARNINGS

- *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Polymyxin B for Injection, and may range in severity from mild diarrhea to fatal colitis.
- If CDAD is suspected or confirmed ongoing, antibiotic use not directed at *C. Difficile* may need to be discontinued.

PRECAUTIONS

- Prescribing polymyxin B in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide a benefit to the patient and increases the risk of the development of drug resistant bacteria.
- Baseline renal function should be done prior to therapy, with frequent monitoring of renal function and blood levels of the drug during parenteral therapy.
- Avoid concurrent use of a curaiform muscle relaxant and other neurotoxic drugs which may precipitate respiratory depression. If signs of respiratory paralysis appear, respiration should be assisted as required, and the drug discontinued.
- As with other antibiotics, use of Polymyxin B for Injection may result in overgrowth of nonsusceptible organisms, including fungi.
- If superinfection occurs, appropriate therapy should be instituted.

ADVERSE REACTIONS

- Nephrotoxic reactions: Albuminuria, cylinduria, azotemia may occur with use of Polymyxin B for Injection without any increase in dosage.
- Neurotoxic reactions: Facial flushing, dizziness, progressing to ataxia, drowsiness, peripheral paresthesias (circumoral and stocking glove), apnea due to concurrent use of curaiform muscle relaxant, other neurotoxic drugs or inadvertent overdosage and signs of meningeal irritation with intrathecal administration may occur with use of Polymyxin B for Injection.
- Other reactions occasionally reported are drug fever, urticarial rash, pain (severe) at intramuscular injection sites, and thrombophlebitis at intravenous injection sites.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for POLYMYXIN B for Injection, USP.

Prochlorperazine Edisylate Injection, USP

10 mg per 2 mL | NDC 70860-778-02

50 mg per 10 mL | NDC 70860-778-10

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THE NEXT GENERATION OF PHARMACY INNOVATION

Prochlorperazine Edisylate Injection, USP

10 mg

NDC 70860-778-02
10 mg per 2 mL

DESCRIPTION	Glass Vial
CONCENTRATION	5 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

50 mg

NDC 70860-778-10
50 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	5 mg per mL
CLOSURE	13 mm
UNIT OF SALE	1 vial
BAR CODED	Yes

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PROCHLORPERAZINE EDISYLATE Injection, USP

INDICATIONS AND USAGE

- To control severe nausea and vomiting.
- For the treatment of schizophrenia.
- Prochlorperazine Edisylate Injection, USP has not been shown effective in the management of behavioral complications in patients with mental retardation.

IMPORTANT SAFETY INFORMATION

WARNING:

INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE AT AN INCREASED RISK OF DEATH. ANALYSES OF SEVENTEEN PLACEBO-CONTROLLED TRIALS (MODAL DURATION OF 10 WEEKS), LARGELY IN PATIENTS TAKING ATYPICAL ANTIPSYCHOTIC DRUGS, REVEALED A RISK OF DEATH IN DRUG-TREATED PATIENTS OF BETWEEN 1.6 TO 1.7 TIMES THE RISK OF DEATH IN PLACEBO-TREATED PATIENTS. OVER THE COURSE OF A TYPICAL 10-WEEK CONTROLLED TRIAL, THE RATE OF DEATH IN DRUG-TREATED PATIENTS WAS ABOUT 4.5%, COMPARED TO A RATE OF ABOUT 2.6% IN THE PLACEBO GROUP. ALTHOUGH THE CAUSES OF DEATH WERE VARIED, MOST OF THE DEATHS APPEARED TO BE EITHER CARDIOVASCULAR (E.G., HEART FAILURE, SUDDEN DEATH) OR INFECTIOUS (E.G., PNEUMONIA) IN NATURE. OBSERVATIONAL STUDIES SUGGEST THAT, SIMILAR TO ATYPICAL ANTIPSYCHOTIC DRUGS, TREATMENT WITH CONVENTIONAL ANTIPSYCHOTIC DRUGS MAY INCREASE MORTALITY. THE EXTENT TO WHICH THE FINDINGS OF INCREASED MORTALITY IN OBSERVATIONAL STUDIES MAY BE ATTRIBUTED TO THE ANTIPSYCHOTIC DRUG AS OPPOSED TO SOME CHARACTERISTIC(S) OF THE PATIENTS IS NOT CLEAR. PROCHLORPERAZINE EDISYLATE INJECTION, USP IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

CONTRAINDICATIONS

- Do not use in patients with known hypersensitivity to phenothiazines.
- Do not use in comatose states or in the presence of large amounts of central nervous system depressants (alcohol, barbiturates, narcotics, etc.).
- Do not use in pediatric surgery.
- Do not use in pediatric patients under 2 years of age or under 20 lbs. Do not use in children for conditions for which dosage has not been established.

WARNINGS

- Prochlorperazine Edisylate Injection is not approved for the treament of patients with dementia-related psychosis.
- The extrapyramidal symptoms which can occur secondary to prochlorperazine may be confused with the central nervous system signs of an undiagnosed primary disease responsible for the vomiting, e.g., Reye's syndrome or other encephalopathy. The use of prochlorperazine and other potential hepatotoxins should be avoided in children and adolescents whose signs and symptoms suggest Reye's syndrome.
- Antipsychotic drugs should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that, 1) is known to respond to antipsychotic drugs, and, 2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of tardive dyskinesia appear in a patient on antipsychotics, drug discontinuation should be considered. However, some patients may require treatment despite the presence of the syndrome.
- A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and, 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.
- Prochlorperazine may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.
- An encephalopathic syndrome (characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms, leukocytosis, elevated serum enzymes, BUN and FBS) has occurred in a few patients treated with lithium plus an antipsychotic. In some instances, the syndrome was followed by irreversible brain damage. Because of a possible causal relationship between these events and the concomitant administration of lithium and antipsychotics, patients receiving such combined therapy should be monitored closely for early evidence of neurologic toxicity and treatment discontinued promptly if such signs appear. This encephalopathic syndrome may be similar to or the same as neuroleptic malignant syndrome (NMS).
- Patients with bone marrow depression or who have previously demonstrated a hypersensitivity reaction (e.g., blood dyscrasias, jaundice) with a phenothiazine should not receive any phenothiazine, including prochlorperazine, unless in the judgment of the physician the potential benefits of treatment outweigh the possible hazards.
- Prochlorperazine may impair mental and/or physical abilities, especially during the first few days of therapy. Therefore, caution patients about activities requiring alertness (e.g., operating vehicles or machinery).
- Phenothiazines may intensify or prolong the action of central nervous system depressants (e.g., alcohol, anesthetics, narcotics).
- Prochlorperazine Edisylate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Caution should be exercised when prochlorperazine is administered to a nursing woman.

PRECAUTIONS

- Leukopenia/neutropenia and agranulocytosis have been reported temporally related to antipsychotic agents. Monitor blood counts and discontinue Prochlorperazine Edisylate at the first sign of a decline of white blood cell count in the absence of causative factors, or if absolute neutrophil count is <1,000/mm3.
- Prochloperazine's antiemetic action may mask signs and symptoms of overdosage or toxicities of other drugs.
- Use cautiously in patients with impaired cardiovascular systems to avoid hypotension.
- Aspiration of vomitus has occurred in postsurgical patients.
- Deep sleep, from which patients can be aroused, and coma have been reported, usually with overdosage.
- Use with caution in patients with glaucoma.
- Use with caution in persons who will be exposed to extreme heat.
- Phenothiazines can diminish the effect of oral anticoagulants.
- Phenothiazines can produce alpha-adrenergic blockade.
- Thiazide diuretics may accentuate the orthostatic hypotension that may occur with phenothiazines.
- Antihypertensive effects of guanethidine and related compounds may be counteracted when used concomitantly with phenothiazines.
- Concomitant use with propranolol may result in increased plasma levels of both drugs.
- Adjustment of anticonvulsant dosage may be necessary.

- Phenothiazines may interfere with metabolism of phenytoin causing phenytoin toxicity.
- Phenothiazines may produce false-positive phenylketonuria (PKU) test results.
- Some patients on long-term antipsychotic therapy may develop tardive dyskinesia. Assess regularly to determine whether to lower the dose or discontinue therapy.
- Prochlorperazine Edisylate may cause dystonia and other neuromuscular reactions. Use under close supervision in children with acute illnesses (e.g., chickenpox, CNS infections, measles, gastroenteritis) or dehydration.
- Do not use phenothiazine derivatives with metrizamide.

ADVERSE REACTIONS

- Common adverse reactions reported with Prochlorperazine Edisylate include drowsiness, dizziness, amenorrhea, blurred vision, skin reactions.
- Other adverse reactions include: neuromuscular (extrapyramidal) reactions, motor restlessness, dystonia, pseudoparkinsonism, tardive dyskinesia, contact dermatitis, and EKG changes.

OVERDOSAGE

- Symptoms: Primarily involvement of the extrapyramidal mechanism producing dystonic reactions. Symptoms of central nervous system depression to the point of somnolence or coma. Agitation and restlessness may also occur. Other possible manifestations include convulsions, EKG changes and cardiac arrhythmias, fever, and autonomic reactions such as hypotension, dry mouth and ileus.
- Treatment: It is important to determine other medications taken by the patient since multiple drug therapy is common in overdosage situations. Treatment is essentially symptomatic and supportive. Keep patient under observation and maintain an open airway, since involvement of the extrapyramidal mechanism may produce dysphagia and respiratory difficulty in severe overdosage. Extrapyramidal symptoms may be treated with antiparkinsonism drugs, barbiturates, or diphenhydramine. Care should be taken to avoid increasing respiratory depression. If administration of a stimulant is desirable, amphetamine, dextroamphetamine, or caffeine and sodium benzoate is recommended. Stimulants that may cause convulsions (e.g., picrotoxin or pentylenetetrazol) should be avoided.
- If hypotension occurs, the standard measures for managing circulatory shock should be initiated. If it is desirable to administer a vasoconstrictor, norepinephrine or phenylephrine are most suitable. Other pressor agents, including epinephrine, are not recommended because phenothiazine derivatives may reverse the usual elevating action of these agents and cause a further lowering of blood pressure.
- Limited experience indicates that phenothiazines are not dialyzable.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for PROCHLORPERAZINE EDISYLATE Injection, USP.

Rocuronium
Bromide Injection

50 mg per 5 mL | NDC 70860-651-05

100 mg per 10 mL | NDC 70860-651-10

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THE NEXT GENERATION OF PHARMACY INNOVATION

Rocuronium

Bromide Injection

50 mg

NDC 70860-651-05
50 mg per 5 mL

DESCRIPTION	Glass Vial
CONCENTRATION	10 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

100 mg

NDC 70860-651-10
100 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	10 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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Terbutaline
Sulfate Injection, USP

1 mg per mL | NDC 70860-801-01

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THE NEXT GENERATION OF PHARMACY INNOVATION

Terbutaline

Sulfate Injection, USP

1 mg

NDC 70860-801-01
1 mg per mL

DESCRIPTION	Glass Vial
CONCENTRATION	1 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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TERBUTALINE SULFATE Injection, USP

INDICATIONS AND USAGE

- Terbutaline sulfate injection is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema.

IMPORTANT SAFETY INFORMATION

WARNING: PROLONGED TOCOLYSIS

TERBUTALINE SULFATE HAS NOT BEEN APPROVED FOR AND SHOULD NOT BE USED FOR PROLONGED TOCOLYSIS (BEYOND 48 TO 72 HOURS). IN PARTICULAR, TERBUTALINE SULFATE SHOULD NOT BE USED FOR MAINTENANCE TOCOLYSIS IN THE OUTPATIENT OR HOME SETTING. SERIOUS ADVERSE REACTIONS, INCLUDING DEATH, HAVE BEEN REPORTED AFTER ADMINISTRATION OF TERBUTALINE SULFATE TO PREGNANT WOMEN. IN THE MOTHER, THESE ADVERSE REACTIONS INCLUDE INCREASED HEART RATE, TRANSIENT HYPERGLYCEMIA, HYPOKALEMIA, CARDIAC ARRHYTHMIAS, PULMONARY EDEMA AND MYOCARDIAL ISCHEMIA. INCREASED FETAL HEART RATE AND NEONATAL HYPOGLYCEMIA MAY OCCUR AS A RESULT OF MATERNAL ADMINISTRATION.

CONTRAINDICATIONS

- Prolonged Tocolysis- Terbutaline sulfate has not been approved for and should not be used for prolonged tocolysis (beyond 48 to 72 hours). In particular, terbutaline sulfate should not be used for maintenance tocolysis in the outpatient or home setting [see Boxed Warning, Prolonged Tocolysis]
- Hypersensitivity- Terbutaline sulfate injection is contraindicated in patients known to be hypersensitive to sympathomimetic amines or any component of this drug product.

WARNINGS

- Asthma may deteriorate acutely over a period of hours or chronically over several days or longer.
- The use of beta-adrenergic agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids.
- Terbutaline sulfate should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Terbutaline sulfate can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. If these effects occur, the drug may need to be discontinued.
- There have been rare reports of seizures in patients receiving terbutaline; seizures did not recur in these patients after the drug was discontinued.

PRECAUTIONS

- Terbutaline, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, including ischemic heart disease, hypertension, and cardiac arrhythmias; in patients with hyperthyroidism or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines or who have convulsive disorders.
- Immediate hypersensitivity reactions and exacerbations of bronchospasm have been reported after terbutaline administration.
- Beta-adrenergic agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation.
- Large doses of intravenous terbutaline have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis.
- Terbutaline sulfate should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.
- Terbutaline sulfate should be used during nursing only if the potential benefit justifies the possible risk to the newborn.

ADVERSE REACTIONS

- Common adverse reactions reported with terbutaline sulfate include tremor, nervousness, dizziness, headache, drowsiness, heart palpitations, tachycardia, dyspnea, chest discomfort, nausea, vomiting, weakness, flushed feeling, sweating, and pain at injection site.

OVERDOSAGE

- There is no specific antidote for terbutaline overdose. The expected symptoms with overdosage are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the adverse reactions listed above.
- Treatment consists of discontinuation of terbutaline sulfate injection together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm.
- There is insufficient evidence to determine if dialysis is beneficial for overdosage of terbutaline sulfate injection.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for TERBUTALINE SUFLATE Injection, USP.

AccuraSEE™ PACKAGING & LABELING

Athenex

Tranexamic Acid

Injection

1,000 mg per 10 mL | NDC 70860-400-10

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- **BIG, BOLD AND BRIGHT —
TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT**
- **DIFFERENTIATION IN EVERY LABEL,
DESIGNED TO HELP REDUCE MEDICATION ERRORS**

THE NEXT GENERATION OF PHARMACY INNOVATION

Tranexamic Acid

Injection

1000 mg

NDC 70860-400-10
1,000 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	100 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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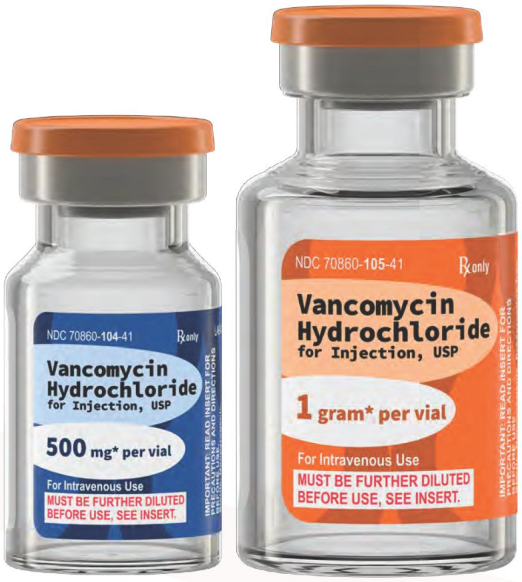
Vancomycin

Hydrochloride for Injection, USP

500 mg per vial | NDC 70860-104-10

1 gram per vial | NDC 70860-105-20



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THE NEXT GENERATION OF PHARMACY INNOVATION

Vancomycin

Hydrochloride for Injection, USP

500 mg

NDC 70860-104-10
500 mg per vial

DESCRIPTION	Glass Vial
CONCENTRATION	500 mg per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

1 g

NDC 70860-105-20
1 gram per vial

DESCRIPTION	Glass Vial
CONCENTRATION	1 gram per vial
CLOSURE	20 mm
UNIT OF SALE	10 vials
BAR CODED	Yes

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EPINEPHrine
Injection

IN 0.9% SODIUM CHLORIDE, STRENGTHS

2 mg per 250 mL BAG	|	NDC 76154-465-15
4 mg per 250 mL BAG	|	NDC 76154-466-15
8 mg per 250 mL BAG	|	NDC 76154-470-15
10 mg per 250 mL BAG	|	NDC 76154-469-15

THE NEXT GENERATION OF PHARMACY INNOVATION

503B

To order, call 1-888-629-8593 or apsorders@athenex.com

EPINEPHrine

Injection

2 mg — NDC 76154-465-15 — 2 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

4 mg — NDC 76154-466-15 — 4 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

8 mg — NDC 76154-470-15 — 8 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

10 mg — NDC 76154-469-15 — 10 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

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Examples of compounding services

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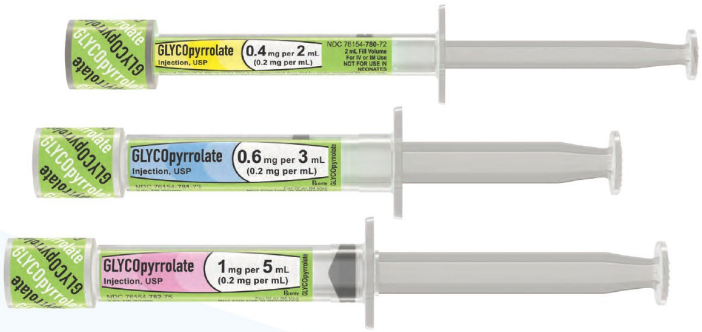
GLYCOpyrrolate

Injection, USP

0.4 mg per 2 mL	|	NDC 76154-780-72
0.6 mg per 3 mL	|	NDC 76154-781-73
1 mg per 5 mL	|	NDC 76154-782-75



• FDA Inspected, cGMP-Compliant Facility • Unique Label Design for Every Product • Barcoded • Expiration Date • Lot Number •

THE NEXT GENERATION OF PHARMACY INNOVATION

503B

To order, call 1-888-629-8593 or apsorders@athenex.com

GLYCOpyrrolate

Injection, USP

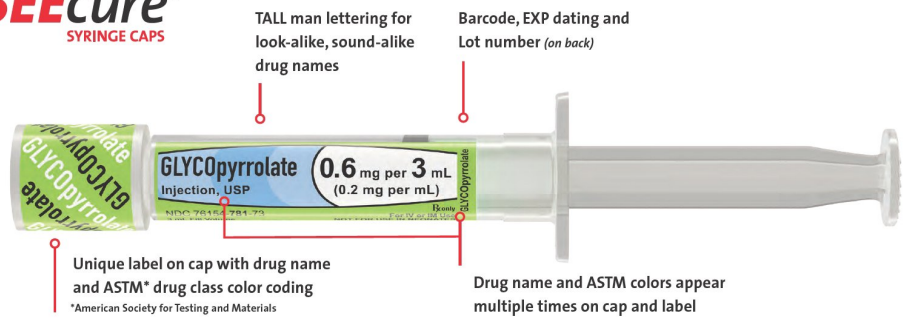
0.4 mg	NDC 76154-780-72 0.4 mg per 2 mL
DESCRIPTION	3 mL Syringe
CONCENTRATION	0.2 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

0.6 mg	NDC 76154-781-73 0.6 mg per 3 mL
DESCRIPTION	5 mL Syringe
CONCENTRATION	0.2 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

1 mg	NDC 76154-782-75 1 mg per 5 mL
DESCRIPTION	5 mL Syringe
CONCENTRATION	0.2 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

FEATURING

SEEcure℠ SYRINGE CAPS



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Neostigmine

Methylsulfate Injection, USP

2 mg per 2 mL	|	NDC 76154-776-72
3 mg per 3 mL	|	NDC 76154-777-73
4 mg per 4 mL	|	NDC 76154-778-74
5 mg per 5 mL	|	NDC 76154-779-75

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THE NEXT GENERATION OF PHARMACY INNOVATION

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To order, call 1-888-629-8593 or apsorders@athenex.com

Neostigmine

Methylsulfate Injection, USP

2 mg NDC 76154-776-72 — 2 mg per 2 mL

DESCRIPTION	3 mL Syringe
CONCENTRATION	1 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

3 mg NDC 76154-777-73 — 3 mg per 3 mL

DESCRIPTION	5 mL Syringe
CONCENTRATION	1 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

4 mg NDC 76154-778-74 — 4 mg per 4 mL

DESCRIPTION	5 mL Syringe
CONCENTRATION	1 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

5 mg NDC 76154-779-75 — 5 mg per 5 mL

DESCRIPTION	5 mL Syringe
CONCENTRATION	1 mg per mL
UNIT OF SALE	20 syringes
BAR CODED	Yes

FEATURING

SEEcure℠ SYRINGE CAPS

(Drug names on the syringe caps!)

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NORepinephrine

Bitartrate

IN 0.9% SODIUM CHLORIDE, STRENGTHS

4 mg per 250 mL BAG	NDC 76154-474-15
8 mg per 250 mL BAG	NDC 76154-475-15

THE NEXT GENERATION OF PHARMACY INNOVATION

503B

To order, call 1-888-629-8593 or apsorders@athenex.com

NORepinephrine

4 mg — NDC 76154-474-15 — 4 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	10 bags
BAR CODED	Yes

8 mg — NDC 76154-475-15 — 8 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	10 bags
BAR CODED	Yes

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PHENYLephrine

IN 0.9% SODIUM CHLORIDE, STRENGTHS

10 mg per 250 mL BAG	|	NDC 76154-456-15
20 mg per 250 mL BAG	|	NDC 76154-457-15
25 mg per 250 mL BAG	|	NDC 76154-458-15
40 mg per 250 mL BAG	|	NDC 76154-459-15
50 mg per 250 mL BAG	|	NDC 76154-460-15

THE NEXT GENERATION OF PHARMACY INNOVATION

503B

To order, call 1-888-629-8593 or apsorders@athenex.com

PHENYLephrine

10 mg

NDC 76154-456-15
10 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

20 mg

NDC 76154-457-15
20 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

25 mg

NDC 76154-458-15
25 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

40 mg

NDC 76154-459-15
40 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

50 mg

NDC 76154-460-15
50 mg per 250 mL

DILUENT	0.9% Sodium Chloride
DESCRIPTION	Premix bag
UNIT OF SALE	24 bags
BAR CODED	Yes

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With a unique label design for every Athenex product, we're offering pharmacists added AccuraSEE for your pharmacy – and for your patients' safety. The idea is simple: "So what you see is *exactly* what you get."

Athenex

Pipeline

Our robust clinical pipeline includes small molecule, biologic and cellular therapies for the treatment of cancer. The Athenex team continues to fuel the rapid expansion of this clinical pipeline now comprised of nine total IND's.

Our Orascovery oral absorption technology, using our novel, highly-selective P-gp pump inhibitor, encequidar (formerly known as HM30181A), in combination with widely-used cytotoxic agents, enables oral administration of currently injectable-only drugs. We have two Src Kinase/tubulin polymerization inhibitors, tirbanibulin (formerly known as KX2-391) and KX2-361, that are being developed both orally for cancers such as glioblastoma, as well as topically for the pre-cancerous disease actinic keratosis. On the biologics front, we have PT01 (also known as Pegtomarginase), which is an enzyme capable of depleting tumors of a key resource for their growth and survival, namely the amino acid arginine. Lastly, we have our TCR-T Immunotherapy platform, which harnesses and enhances the patient's own immune system to target and eliminate cancer.

Taken together, our clinical pipeline balances a range of therapeutic approaches for the treatment of cancer to enable us to improve the lives of cancer patients.

Program	Drug Candidate	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3
Orascovery (P-gp inhibitor [encequidar] + chemoRx agents)	Oral paclitaxel + encequidar (Oraxol)	Metastatic breast cancer				
		Angiosarcoma				
	Oral paclitaxel + encequidar (Oraxol) w/ pembrolizumab	Solid tumors				
	Oral paclitaxel + encequidar (Oraxol) w/ ramucirumab*	Gastric cancer				
	Oral irinotecan + encequidar (Oratecan)	Solid tumors				
	Oral docetaxel + encequidar (Oradoxel)	Solid tumors				
	Oral topotecan + encequidar (Oratopo)	Solid tumors				
	Oral eribulin + encequidar (Eribulin ORA)	Solid tumors				
Dual Inhibition	ATNX-04 (CYP / P-gp)	Multiple tumors				
Src Kinase Inhibition	Tirbanibulin (KX2-391) ointment	Actinic keratosis				
		Psoriasis				
		Skin cancers				
	Tirbanibulin (KX2-391) oral	Liquid tumors / Ovarian cancer				
	KX2-361 (KX-02)	Glioblastoma				
TCR-T Immunotherapy	TAEST16001	Multiple tumors				
Arginine Deprivation Therapy	(PT-01) Pegtomarginase	Multiple tumors				

* Collaboration with Eli Lilly and Company, makers of ramucirumab

Technology Platforms

Orascovery

Src Inhibition

Arginine Deprivation Therapy

TCR-T Immunotherapy

Dual Inhibition

Program	Drug Candidate	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3
Orascovery (P-gp inhibitor [encequidar] + chemoRx agents)	Oral paclitaxel + encequidar (Oraxol)	Metastatic breast cancer				
		Angiosarcoma				
	Oral paclitaxel + encequidar (Oraxol) w/ pembrolizumab	Solid tumors				
	Oral paclitaxel + encequidar (Oraxol) w/ ramucirumab*	Gastric cancer				
	Oral irinotecan + encequidar (Oratecan)	Solid tumors				
	Oral docetaxel + encequidar (Oradoxel)	Solid tumors				
	Oral topotecan + encequidar (Oratopo)	Solid tumors				
	Oral eribulin + encequidar (Eribulin ORA)	Solid tumors				
Dual Inhibition	ATNX-04 (CYP / P-gp)	Multiple tumors				
Src Kinase Inhibition	Tirbanibulin (KX2-391) ointment	Actinic keratosis				
		Psoriasis				
		Skin cancers				
	Tirbanibulin (KX2-391) oral	Liquid tumors / Ovarian cancer				
	KX2-361 (KX-02)	Glioblastoma				
TCR-T Immunotherapy	TAEST16001	Multiple tumors				
Arginine Deprivation Therapy	(PT-01) Pegtomarginase	Multiple tumors				

* Collaboration with Eli Lilly and Company, makers of ramucirumab

Technology Platforms

Orascovery

Src Inhibition

Arginine Deprivation Therapy

TCR-T Immunotherapy

Dual Inhibition

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