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sure the tip of the needle is in the fluid. Slowly pull back on the plunger (Figure 11) to the mark that matches your prescribed dose (usually the 0.4 mL mark which is an 8 mg dose or the 0.6 mL mark which is a 12 mg dose).

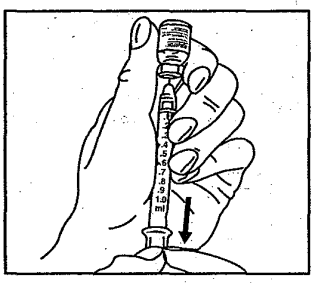

Figure 11

You may see some fluid or bubbles inside the vial when the syringe is filled. This is normal.

8. With the needle still in the vial, gently tap the syringe to make any air bubbles rise to the top (Figure 12).

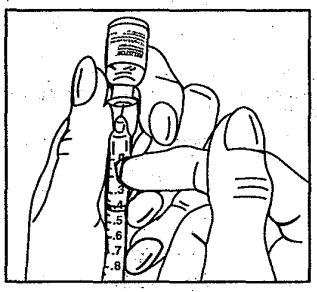

Figure 12

9. Slowly push the plunger up until all air bubbles are out of the syringe (Figure 13).

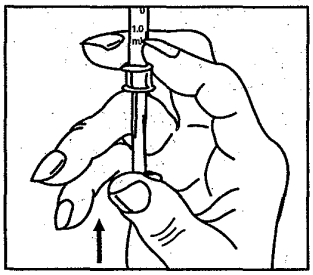

Figure 13

10. Make sure the tip of the needle is in the fluid. Slowly pull back the plunger to draw the right amount of liquid back into the syringe (Figure 14).

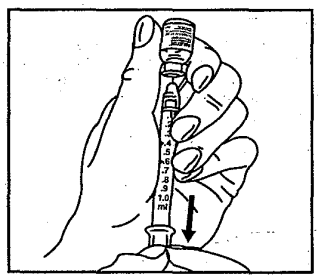

Figure 14

Check to be sure that you have the right dose of RELISTOR in the syringe.

Note: A small air bubble may stay in the syringe. This is okay and it will not affect the dose of medicine in the syringe.

11. Slowly withdraw the needle from the vial (do not touch the needle or allow the needle to touch any surface). Safely throw away the unused medicine in the vial. See Step 5.

Step 4: Injecting RELISTOR

1. Pinch the skin around the injection site as you were instructed (Figure 15).

Figure 15

2. Insert the full length of the needle into the skin at 45-degree angle with a "quick dart-like" motion (Figure 16).

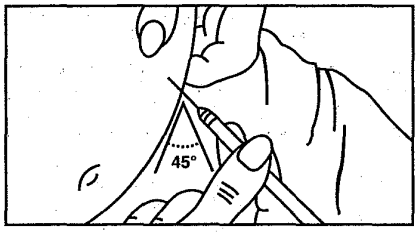

Figure 16

3. Let go of the skin and slowly push down on the plunger past the resistance point, until the syringe is empty and you hear a click (Figure 17).

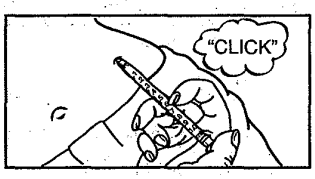

Figure 17

4. The click sound means that the needle (Figure 18) has been retracted (pulled back) into the syringe barrel (Figure 19).

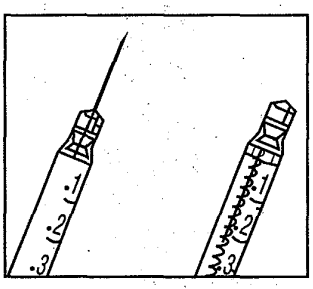

Figure 18 Figure 19

5. Hold a cotton ball or gauze over the injection site (Figure 20). Do not rub the injection site. Apply an adhesive bandage to the injection site if needed.

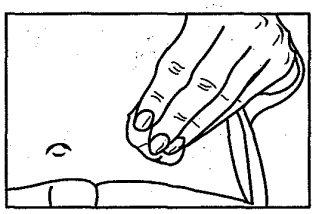

Figure 20

Step 5: Disposing of supplies

- **Do not** re-use a syringe or needle.
- **Do not** recap a used needle.
- Place used needles, syringes and vials in a closeable, puncture-resistant container. You may use a sharps container (such as a red biohazard container), a hard plastic container (such as a detergent bottle), or a metal container (such as an empty coffee can). Ask your healthcare provider for instructions on the right way to throw away (dispose of) the container. There may be state and local laws about how you should throw away used needles and syringes.
- **If you have any questions, talk to your healthcare provider or pharmacist.**

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BUTRANS™

[*BYOO-trans*]
(buprenorphine)
Transdermal System for Transdermal Administration

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Butrans™ safely and effectively. See full prescribing information for Butrans.

Butrans (buprenorphine) Transdermal System for transdermal administration CIII
Initial U.S. Approval: 1981

WARNING: POTENTIAL FOR ABUSE and IMPORTANCE OF PROPER PATIENT SELECTION

See full prescribing information for complete boxed warning.

- **Butrans is indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. (1)**
- **Butrans contains buprenorphine which is a mu opioid partial agonist and a Schedule III controlled substance. (9.1)**
- **Assess patients for their clinical risks for opioid abuse or addiction prior to prescribing opioids. (2.2)**
- **Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongations. (2.3)**
- **Avoid exposing the Butrans application site and surrounding area to direct external heat sources. Temperature-dependent increases in buprenorphine release from the system may result in overdose and death. (5.11)**

INDICATIONS AND USAGE

Butrans is indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. (1)

DOSAGE AND ADMINISTRATION

- Each Butrans is intended to be worn for 7 days. (2.1)
- In opioid-naïve patients, the initial dose of Butrans should always be 5 mcg/hour. (2.2)
- For patients already receiving opioids, consult conversion instructions. (2.2)
- Do not increase the Butrans dose until the patient has been exposed continually to the previous dose for 72 hours. (2.3)
- After removal, wait a minimum of 3 weeks before applying to the same site (2.1)
- When Butrans is no longer required by the patient, taper the dose as part of a comprehensive treatment plan. (2.5)

DOSAGE FORMS AND STRENGTHS

- **Transdermal system,** 5 mcg/hour, 10 mcg/hour, and 20 mcg/hour. (3)

CONTRAINDICATIONS

- Patients who have significant respiratory depression (4, 5.1, 5.2)

patients who have severe bronchial asthma (4)
patients who have or are suspected of having paralytic ileus (4, 5.16)
patients who have known hypersensitivity to any of its components or the active ingredient, buprenorphine (4)
the management of acute pain or in patients who require opioid analgesia for a short period of time (4)
the management of post-operative pain, including use after out-patient or day surgeries (4)
the management of mild pain (4)
the management of intermittent pain (e.g., use on an as-needed basis [prn]) (4)

WARNINGS AND PRECAUTIONS

Use with extreme caution in patients at risk of respiratory depression. (5.1, 7.2)
Use with caution in patients who are receiving other central nervous system (CNS) depressants. (5.2, 7.2, 12.2) Additive CNS effects are expected when used with alcohol, benzodiazepines, other opioids, or illicit drugs. (5.3, 7.2)
Use in patients with Long QT Syndrome, family history of Long QT Syndrome, or those taking Class IA or Class III antiarrhythmic medications. (5.4, 12.2)
Butrans may worsen increased intracranial pressure and obscure its signs, such as level of consciousness or pupillary signs. (5.5)
Use with caution in patients at increased risk of hypotension and in patients in circulatory shock. (5.6, 12.2)
Ileus may occur. Monitor for decreased bowel motility in postoperative patients. (5.16)
Use with caution in patients with biliary tract disease, including acute pancreatitis. (5.16)

ADVERSE REACTIONS

The common adverse reactions (≥5%) include: nausea, headache, application site pruritus, dizziness, constipation, somnolence, vomiting, application site erythema, dry mouth and application site rash.
To report **SUSPECTED ADVERSE REACTIONS, contact** Purdue Pharma L.P. at 1-888-726-7535 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

Agents that induce CYP3A4 enzymatic activity may alter the metabolism of buprenorphine but the clinical significance of these interactions is not known. (7.1)
CNS depressants may interact with Butrans resulting in respiratory and CNS depression - use caution in prescribing Butrans for patients receiving benzodiazepines or other depressants and warn patients against concomitant use, administration/misuse. (7.2)
Muscle relaxants may enhance the action of Butrans and produce an increased degree of respiratory depression. (7.2)

USE IN SPECIFIC POPULATIONS

Pregnancy: Butrans is not recommended for use during pregnancy. (8.1)
Nursing Mothers: Breast-feeding is not advised in mothers treated with Butrans. (8.3)
Pediatric Use: Safety and effectiveness of Butrans have not been established in patients below 18 years. (8.4)
Geriatric Use: While no dose adjustment is recommended on the basis of age, administer Butrans with caution in elderly patients. (8.5)
Hepatic Impairment: Butrans has not been evaluated in patients with severe hepatic impairment and should be administered with caution. (8.6)
See 17 for **PATIENT COUNSELING INFORMATION** and **Medication Guide.**

Revised: August 2010

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: IMPORTANCE OF PROPER PATIENT SELECTION, POTENTIAL FOR ABUSE, AND LIMITATIONS OF USE

Proper Patient Selection

Butrans is a transdermal formulation of buprenorphine indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. (1)

Potential for Abuse

Butrans contains buprenorphine which is a mu opioid partial agonist and a Schedule III controlled substance. Butrans can be abused in a manner similar to other opioid agonists, legal or illicit. Consider the abuse potential when prescribing or dispensing Butrans in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. (9)

Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Assess patients for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. Routinely monitor all patients receiving opioids for signs of misuse, abuse and addiction. (2.2)

Limitations of Use

Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongation. (2.3) Avoid exposing the Butrans application site and surrounding area to direct external heat sources. Temperature-dependent increases in buprenorphine release from the system may result in overdose and death. (5.11)

1 INDICATIONS AND USAGE

Butrans is indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time.

2 DOSAGE AND ADMINISTRATION

2.1 General Principles

Selection of patients for treatment with Butrans is governed by the same principles that apply to the use of similar opioid analgesics. Physicians should individualize treatment in every case, using non-opioid analgesics, opioids on an as-needed basis and/or combination products, and chronic opioid therapy in a progressive plan of pain management such as outlined by the World Health Organization, the American Pain Society, and Federation of State Medical Boards Model Policy.

Butrans is for transdermal use (on intact skin) only.

Do not use Butrans if the pouch seal is broken or the patch is cut, damaged, or changed in any way. Do not cut Butrans.

Each Butrans is intended to be worn for 7 days.

Apply Butrans to the upper outer arm, upper chest, upper back or the side of the chest. These four sites (each present on both sides of the body) provide 8 possible application sites. Rotate Butrans among the 8 described skin sites. After Butrans removal, wait a minimum of 21 days before reapplying to the same skin site *[see Clinical Pharmacology (12.3)]*.

Apply Butrans to a hairless or nearly hairless skin site. If none are available, the hair at the site should be clipped, not shaven. Do not apply Butrans to irritated skin. If the application site must be cleaned, clean the site with water only. Do not use soaps, alcohol, oils, lotions, or abrasive devices. Allow the skin to dry before applying Butrans.

If problems with adhesion of Butrans occur, the edges may be taped with first aid tape.

If Butrans falls off during the 7 days dosing interval, dispose of the transdermal system properly and place a new Butrans on at a different skin site *[see How Supplied/Storage and Handling (16)]*.

2.2 Initiation of Therapy

It is critical to initiate the dosing regimen individually for each patient. Overestimating the Butrans dose when converting patients from another opioid medication can result in fatal overdose with the first dose *[see Overdosage (10)]*. Consider the following when selecting the initial dose of Butrans:

1. The total daily dose, potency, and specific characteristics of the opioid the patient has been taking previously;
2. The reliability of the relative potency estimate used to calculate the equivalent buprenorphine dose needed (when converting from other opioids or opioid-combination products);
3. The patient's degree of tolerance to the respiratory-depressant and sedating effects of opioids;
4. The age, general condition, and medical status of the patient;
5. Concurrent non-opioid analgesic and other medications;
6. The type and severity of the patient's pain;
7. The balance between pain control and adverse drug experiences;
8. Risk factors for abuse, addiction, or diversion, including a prior history of abuse, addiction, or diversion.

The following dosing recommendations, therefore, can only be considered as suggested approaches to what is actually a series of clinical decisions over time in the management of the pain of each individual patient.

Opioid-Naïve Patients

For opioid-naïve patients, initiate treatment with Butrans 5 mcg/hour. Thereafter, individually titrate the dose as described in Section 2.3 Dose Titration to a level that provides adequate analgesia and minimizes side effects. Dose may be titrated to the next higher level after a minimum of 72 hours.

Conversion from Other Opioids to Butrans

There is a potential for buprenorphine to precipitate withdrawal in patients who are already on opioids. For conversion from other opioids to Butrans (see Table 1), taper the patient's current around-the-clock opioids for up to 7 days to no more than 30 mg of morphine or equivalent per day before beginning treatment with Butrans. Patients may use short-acting analgesics as needed until analgesic efficacy with Butrans is attained.

For patients whose daily dose was less than 30 mg of oral morphine or equivalent, initiate treatment with Butrans 5 mcg/hour. For patients whose daily dose was between 30 and 80 mg morphine equivalents, initiate treatment with Butrans 10 mcg/hour (see Table 1). Thereafter, individually titrate the dose as described in Section 2.3 Dose Titration.

Table 1: Dose Estimation for Conversion of Oral Morphine Equivalents to Butrans

Current Opioid Analgesic	Current Daily Dose	
Oral Morphine Equivalent	<30 mg	30-80 mg
	↓	↓
Recommended Butrans Starting Dose	5 mcg/hour	10 mcg/hour

Use caution when prescribing Butrans to opioid-experienced patients requiring high doses of opioids (more

than 80 mg/day of oral morphine equivalents). Butrans 20 mcg/hour may not provide adequate analgesia for patients requiring greater than 80 mg/day oral morphine equivalents.

2.3 Dose Titration

Based on the patient's requirement for supplemental short-acting analgesics, upward titration may be instituted with a minimum Butrans titration interval of 72 hours, based on the pharmacokinetic profile and time to reach steady state levels *[see Clinical Pharmacology (12.3)]*. Individually titrate the dose, under close supervision, to a level that provides adequate analgesia with tolerable side effects.

The maximum Butrans dose is 20 mcg/hour. **Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongation.** In a clinical trial, Butrans 40 mcg/hour (given as two Butrans 20 mcg/hour systems) resulted in prolongation of the QTc interval *[see Warnings and Precautions (5.4) and Clinical Pharmacology (12.2)]*.

During periods of changing analgesic requirements, including initial titration, frequent contact is recommended between the prescriber, other members of the healthcare team, the patient, and the caregiver/family. Advise patients and caregivers/family members of the potential side effects.

2.4 Maintenance of Therapy and Supplemental Analgesia

The intent of the titration period is to establish a patient-specific weekly Butrans dose that will maintain adequate analgesia with tolerable side effects for as long as pain management is necessary. Immediate-release opioid and non-opioid medications can be used as supplemental analgesia during Butrans therapy.

During chronic opioid analgesic therapy with Butrans, reassess the continued need for around-the-clock opioid analgesic therapy periodically.

2.5 Cessation of Therapy

When the patient no longer requires therapy with Butrans, taper the dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient; consider introduction of an appropriate immediate-release opioid medication. Undertake discontinuation of therapy as part of a comprehensive treatment plan.

2.6 Patients with Hepatic Impairment

Start patients with mild to moderate hepatic impairment with the Butrans 5 mcg/hour dose. Thereafter, individually titrate the dose to a level that provides adequate analgesia and tolerable side effects, under the close supervision of the prescriber. Butrans has not been evaluated in patients with severe hepatic impairment. As Butrans is only intended for 7-day application, consider use of an alternate analgesic that may permit more flexibility with the dosing in patients with severe hepatic impairment *[see Warnings and Precautions (5.1), Use In Specific Populations (8.6), and Clinical Pharmacology (12.3)]*.

3 DOSAGE FORMS AND STRENGTHS

Butrans is available as:

- Butrans 5 mcg/hour Transdermal System (dimensions: 45 mm by 45 mm)
- Butrans 10 mcg/hour Transdermal System (dimensions: 45 mm by 68 mm)
- Butrans 20 mcg/hour Transdermal System (dimensions: 72 mm by 72 mm)

4 CONTRAINDICATIONS

Butrans is contraindicated in:

- patients who have significant respiratory depression
- patients who have severe bronchial asthma
- patients who have or are suspected of having paralytic ileus
- patients who have known hypersensitivity to any of its components or the active ingredient, buprenorphine
- the management of acute pain or in patients who require opioid analgesia for a short period of time
- the management of post-operative pain, including use after out-patient or day surgeries
- the management of mild pain
- the management of intermittent pain (e.g., use on an as needed basis [prn])

5 WARNINGS AND PRECAUTIONS

5.1 Respiratory Depression

Respiratory depression is the chief hazard of Butrans. Respiratory depression occurs more frequently in elderly or debilitated patients as well as those suffering from conditions accompanied by hypoxia or hypercapnia when even moderate therapeutic doses may dangerously decrease pulmonary ventilation, and when opioids, including Butrans, are given in conjunction with other agents that depress respiration.

Profound sedation, unresponsiveness, infrequent deep ("sighing") breaths or atypical snoring frequently accompany opioid-induced respiratory depression.

Use Butrans with extreme caution in patients with any of the following:

- significant chronic obstructive pulmonary disease or cor pulmonale
- other risk of substantially decreased respiratory reserve such as asthma, severe obesity, sleep apnea, myxedema, clinically significant kyphoscoliosis, and central nervous system (CNS) depression
- hypoxia
- hypercapnia
- pre-existing respiratory depression

5.2 CNS Depression

Butrans may cause somnolence, dizziness, alterations in judgment and alterations in levels of consciousness, including coma.

5.3 Interactions with Alcohol, Central Nervous System Depressants, and Illicit Drugs

Hypotension, profound sedation, coma or respiratory depression may result if Butrans is added to a regimen that includes other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, muscle relaxants, other opioids). Therefore, use caution when deciding to initiate therapy with Butrans in patients who are taking other CNS depressants. Take into account the types of other medications being taken, the duration of therapy with them, and the patient's response to those medicines, including the degree of tolerance that has developed to CNS depression. Consider the patient's use, if any, of alcohol and/or illicit drugs that cause CNS depression. If the decision to begin Butrans is made, start with a lower Butrans dose than usual.

Consider using a lower initial dose of a CNS depressant when given to a patient currently taking Butrans due to the potential of additive CNS depressant effects.

5.4 QTc Prolongation

A positive-controlled study of the effects of Butrans on the QTc interval in healthy subjects demonstrated no clinically meaningful effect at a Butrans dose of 10 mcg/hour; however, a Butrans dose of 40 mcg/hour (given as two Butrans 20 mcg/hour Transdermal Systems) was observed to prolong the QTc interval *[see Clinical Pharmacology (12.2)]*.

Consider these observations in clinical decisions when prescribing Butrans to patients with hypokalemia or clinically unstable cardiac disease, including: unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, or active myocardial ischemia. Avoid the use of Butrans in patients with a history of Long QT Syndrome or an immediate family member with this condition, or those taking Class IA antiarrhythmic medications (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic medications (e.g., sotalol, amiodarone, dofetilide).

5.5 Head Injury

The respiratory depressant effects of opioids, including Butrans, include carbon dioxide retention, which can lead to an elevation of cerebrospinal fluid pressure. This effect may be exaggerated in the presence of head injury, intracranial lesions, or other sources of pre-existing increased intracranial pressure. Butrans may produce miosis that is independent of ambient light, and altered consciousness, either of which may obscure neurologic signs associated with increased intracranial pressure in persons with head injuries.

5.6 Hypotensive Effects

Butrans may cause severe hypotension. There is an added risk to individuals whose ability to maintain blood pressure has been compromised by a depleted blood volume, or after concurrent administration with drugs such as phenothiazines or other agents which compromise vasomotor tone. Buprenorphine may produce orthostatic hypotension in ambulatory patients. Administer Butrans with caution to patients in circulatory shock, since vasodilation produced by the drug may further reduce cardiac output and blood pressure.

5.7 Misuse, Abuse, and Diversion of Opioids

Butrans contains buprenorphine, a partial agonist at the mu opioid receptor and a Schedule III controlled substance. Opioid agonists have potential for being abused, are sought by drug abusers and people with addiction disorders, and are subject to criminal diversion.

Butrans can be abused in a manner similar to other opioid agonists, legal or illicit. Consider this potential for abuse when prescribing or dispensing Butrans in situations where the prescriber or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. Monitor all patients receiving opioids for signs of abuse, misuse, and addiction. Furthermore, assess patients for their potential for opioid abuse prior to being prescribed opioid therapy. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse) or mental illness (e.g., depression). Opioids may still be appropriate for use in these patients; however, they will require intensive monitoring for signs of abuse.

Notwithstanding concerns about abuse, addiction, and diversion, provide proper management of pain. However, all patients treated with opioid agonists require careful monitoring for signs of abuse and addiction, since use of opioid agonist analgesic products carries the risk of addiction even under appropriate medical use *[see Drug Abuse and Dependence (9.2)]*. Data are not available to establish the true incidence of addiction in patients with chronic pain treated with opioids.

Abuse of Butrans poses a significant risk to the abuser that could potentially result in overdose or death *[see Drug Abuse and Dependence (9)]*.

Contact your state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product.

5.8 Hepatotoxicity

Although not observed in Butrans chronic pain clinical trials, cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving sublingual buprenorphine for the treatment of opioid dependence, both in clinical trials and through post-marketing adverse event reports. The spectrum of abnormalities ranges from transient asymptomatic elevations in hepatic transaminases to case reports of hepatic failure, hepatic necrosis, hepatorenal syndrome, and hepatic encephalopathy. In many cases, the presence of pre-existing liver enzyme abnormalities, infection with hepatitis B or hepatitis C virus, concomitant usage of other potentially hepatotoxic drugs, and ongoing injection drug abuse may have played a causative or contributory role. In other cases, insufficient data were available to determine the etiology of the abnormality. The possibility exists that buprenorphine had a causative or contributory role in the development of the hepatic abnormality in some cases. For patients at increased risk of hepatotoxicity (e.g., patients with a history of excessive alcohol intake, intravenous drug abuse or liver disease), baseline and periodic monitoring of liver function during treatment with Butrans is recommended. A biological and etiological evaluation is recommended when a hepatic event is suspected.

5.9 Application Site Skin Reactions

In rare cases, severe application site skin reactions with signs of marked inflammation including "burn," "discharge," and "vesicles" have occurred. Time of onset varies, ranging from days to months following the initiation of Butrans treatment. Instruct patients to promptly report the development of severe application site reactions and discontinue therapy.

5.10 Anaphylactic/Allergic Reactions

Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in the post-marketing experience. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported. A history of hypersensitivity to buprenorphine is a contraindication to the use of Butrans.

5.11 Application of External Heat

Advise patients and their caregivers to avoid exposing the Butrans application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, saunas, hot tubs, and heated water beds, etc., while wearing the system because an increase in absorption of buprenorphine may occur *[see Clinical Pharmacology (12.3)]*. Advise patients against exposure of the Butrans application site and surrounding area to hot water or prolonged exposure to direct sunlight. There is a potential for temperature-dependent increases in buprenorphine released from the system resulting in possible overdose and death.

5.12 Patients with Fever

Patients wearing Butrans systems who develop fever or increased core body temperature due to strenuous exertion should be monitored for opioid side effects and the Butrans dose should be adjusted if necessary *[see Dosage and Administration (2.4)]*.

5.13 Driving and Operating Machinery

Butrans may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Caution patients accordingly.

5.14 Seizures

Butrans, as with other opioids, may aggravate seizure disorders, may lower seizure threshold, and therefore, may induce seizures in some clinical settings. Use Butrans with caution in patients with a history of seizure disorders.

5.15 Special Risk Groups

Use Butrans with caution in the following conditions, due to increased risk of adverse reactions: alcoholism; delirium tremens; adrenocortical insufficiency; CNS depression; debilitation; kyphoscoliosis associated with respiratory compromise; myxedema or hypothyroidism; prostatic hypertrophy or urethral stricture; severe impairment of hepatic, pulmonary or renal function; and toxic psychosis.

5.16 Use in Pancreatic/Biliary Tract Disease and Other Gastrointestinal Conditions

Butrans may cause spasm of the sphincter of Oddi. Use with caution in patients with biliary tract disease, including acute pancreatitis. Opioids, including Butrans, may cause increased serum amylase.

The administration of Butrans may obscure the diagnosis or clinical course in patients with acute abdominal conditions. Use Butrans with caution in patients who are at risk of developing ileus.

5.17 Use in Addiction Treatment

Butrans has not been studied and is not approved for use in the management of addictive disorders.

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