PDR®

54 EDITION

2000

PHYSICIANS' DESK REFERENCE®

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MUCO-FEN® 800 DM TABLETS ℞

[mū-co-fin]
Guaifenesin/Dextromehorphan HBr

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Guaifenesin ..... 800 mg
Dextromethorphan Hydrobromide ..... 60 mg

DOSAGE

Adults and children over 12 years of age: 1 tablet every 12 hours not to exceed 2 tablets in 24 hours
Children 6–12 years of age: ½ tablet every 12 hours not to exceed 1 tablet in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-114-10)

MUCO-FEN® 800 Tablets ℞

[mū-co-fin]
Guaifenesin

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Guaifenesin ..... 800 mg

DOSAGE

Adults and children over 12 years of age: 1–1½ tablets every 12 hours not to exceed 3 tablets (2400 mg) in 24 hours
Children 6–12 years of age: ½ tablet every 12 hours not to exceed 1200 mg in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-109-10)

MUCO-FEN® 1200 TABLETS ℞

[mū-co-fin]
Guaifenesin

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Guaifenesin ..... 1200 mg

DOSAGE

Adults and children over 12 years of age: 1 tablet every 12 hours not to exceed 2 tablets (2400 mg) in 24 hours
Children 6–12 years of age: ½ tablet every 12 hours not to exceed 1 tablet (1200 mg) in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-120-10)

MUCO-FEN® DM TABLETS ℞

[mū-co-fin]
Guaifenesin/Dextromethorphan HBr

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Guaifenesin ..... 600 mg
Dextromethorphan Hydrobromide ..... 30 mg

DOSAGE

Adults and children over 12 years of age: 1–2 tablets every 12 hours not to exceed 4 tablets in 24 hours
Children 6–12 years of age: 1 tablet every 12 hours not to exceed 2 tablets in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-108-10)

MUCO-FEN® LA Tablets ℞

[mū-co-fin]
Guaifenesin

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Guaifenesin ..... 600 mg

DOSAGE

Adults and children over 12 years of age: 1–2 tablets every 12 hours not to exceed 4 tablets (2400 mg) in 24 hours
Children 6–12 years of age: 1 tablet every 12 hours not to exceed 2 tablets (1200 mg) in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-102-10)

PROFEN LA® TABLETS ℞

[prō'-fin]
Phenylpropanolamine HCl/Guaifenesin

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Phenylpropanolamine Hydrochloride ..... 75 mg
Guaifenesin ..... 600 mg

DOSAGE

Adults and children over 12 years of age: 1 tablet every 12 hours
Children 6–12 years of age: ½ tablet every 12 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-104-10)

PROFEN II® TABLETS ℞

[prō'-fin]
Phenylpropanolamine HCl/Guaifenesin

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Phenylpropanolamine Hydrochloride ..... 37.5 mg
Guaifenesin ..... 600 mg

DOSAGE

Adults and children over 12 years of age: 1–2 tablets every 12 hours not to exceed 4 tablets in 24 hours
Children 6–12 years of age: 1 tablet every 12 hours not to exceed 2 tablets in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-107-10)

PROFEN II DM® Liquid ℞

[prō'-fin]
Dextromethorphan HBr/Phenylpropanolamine HCl/Guaifenesin

DESCRIPTION

Each 5 mL (one teaspoonful) of PROFEN II DM® LIQUID contains:
Dextromethorphan HBr ..... 10 mg
Phenylpropanolamine HCl ..... 12.5 mg
Guaifenesin ..... 200 mg
In a sugar free, dye free and alcohol free base.

DOSAGE

Adults and children 12 years or older: 1–2 teaspoonfuls every 4 hours not to exceed 12 teaspoonfuls in 24 hours. Children 6–12 years of age: $^1/_2$–1 teaspoonful every 4 hours not to exceed 6 teaspoonfuls in 24 hours. Children 2–6 years of age: $^1/_4$–$^1/_2$ teaspoonful not to exceed 3 teaspoonfuls in 24 hours. Children under 2 years: As directed by physician.

HOW SUPPLIED

PROFEN II DM® LIQUID is available as a sugar, alcohol and dye-free clear liquid having a cherry odor and flavor.
Pint Bottles: NDC 59310-201-16.

PROFEN II DM® TABLETS ℞

[prō '-fin]
Dextromethorphan HBr/Phenylpropanolamine HCl/Guaifenesin

DESCRIPTION

Each time-released, dye free, scored tablet contains:
Dextromethorphan Hydrobromide ..... 30 mg
Phenylpropanolamine Hydrochloride ..... 37.5 mg
Guaifenesin ..... 600 mg

DOSAGE

Adults and children over 12 years of age: 1–2 tablets every 12 hours not to exceed 4 tablets in 24 hours
Children 6–12 years of age: 1 tablet every 12 hours not to exceed 2 tablets in 24 hours

HOW SUPPLIED

Bottles of 100 tablets (NDC 59310-110-10)

Wallace Laboratories

P.O. BOX 1001
CRANBURY, NJ 08512

For Medical Information, Contact:
Generally:
Professional Services
800-526-3840
After Hours and Weekend Emergencies:
(609) 655-6474

Wallace Laboratories
Sales and Ordering:
Div. of Carter-Wallace, Inc
P.O. Box 1001
Cranbury, NJ 08512

AQUATENSEN® ℞

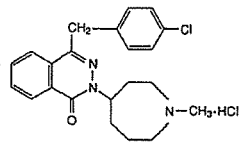
(methyclothiazide tablets, USP, 5 mg)
Tablets

ASTELIN® ℞

(azelastine hydrochloride)
Nasal Spray, 137 mcg
For Intranasal Use Only

DESCRIPTION

Astelin® (azelastine hydrochloride) Nasal Spray, 137 micrograms (mcg), is an antihistamine formulated as a metered-spray solution for intranasal administration. Azelastine hydrochloride occurs as a white, almost odorless, crystalline powder with a bitter taste. It has a molecular weight of 418.37. It is sparingly soluble in water, methanol, and propylene glycol and slightly soluble in ethanol, octanol, and glycerine. It has a melting point of about 225°C and the pH of a saturated solution is between 5.0 and 5.4. Its chemical name is (±)-1-(2H)-phthalazinone,4-[(4-chlorophenyl) methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-, monohydrochloride. Its molecular formula is $C_{22}H_{24}ClN_3O \cdot HCl$ with the following chemical structure:



Astelin® Nasal Spray contains 0.1% azelastine hydrochloride in an aqueous solution at pH 6.8 ± 0.3. It also contains benzalkonium chloride (125 mcg/mL), edetate disodium, hydroxypropyl methyl cellulose, citric acid, dibasic sodium phosphate, sodium chloride, and purified water.
After priming, each metered spray delivers a 0.137 mL mean volume containing 137 mcg of azelastine hydrochloride (equivalent to 125 mcg of azelastine base). Each bottle can deliver 100 metered sprays.

CLINICAL PHARMACOLOGY

Azelastine hydrochloride, a phthalazinone derivative, exhibits histamine H_1-receptor antagonist activity in isolated tissues, animal models, and humans. Astelin® Nasal Spray is administered as a racemic mixture with no difference in pharmacologic activity noted between the enantiomers in *in vitro* studies. The major metabolite, desmethylazelastine, also possesses H_1-receptor antagonist activity.

Pharmacokinetics and Metabolism

After intranasal administration, the systemic bioavailability of azelastine hydrochloride is approximately 40%. Maximum plasma concentrations (Cmax) are achieved in 2–3 hours. Based on intravenous and oral administration, the elimination half-life, steady-state volume of distribution, and plasma clearance are 22 hours, 14.5 L/kg, and 0.5 L/h/kg, respectively. Approximately 75% of an oral dose of radiolabeled azelastine hydrochloride was excreted in the feces with less than 10% as unchanged azelastine. Azelastine is oxidatively metabolized to the principal active metabolite, desmethylazelastine, by the cytochrome P450 enzyme system. The specific P450 isoforms responsible for the biotransformation of azelastine have not been identified; however, clinical interaction studies with the known CYP3A4 inhibitor erythromycin failed to demonstrate a pharmacokinetic interaction. In a multiple-dose, steady-state drug interaction study in normal volunteers, cimetidine (400 mg twice daily), a nosnpecific P450 inhibitor, raised orally administered mean azelastine (4 mg twice daily) concentrations by approximately 65%.
The major active metabolite, desmethylazelastine, was not measurable (below assay limits) after single-dose intranasal administration of azelastine hydrochloride. After intranasal dosing of azelastine hydrochloride to steady-state, plasma concentrations of desmethylazelastine range from 20–50% of azelastine concentrations. When azelastine hydrochloride is administered orally, desmethylazelastine has an elimination half-life of 54 hours. Limited data indicate that the metabolite profile is similar when azelastine hydrochloride is administered via the intranasal or oral route.
In vitro studies with human plasma indicate that the plasma protein binding of azelastine and desmethylazelastine are approximately 88% and 97%, respectively.
Azelastine hydrochloride administered intranasally at doses above two sprays per nostril twice daily for 29 days resulted in greater than proportional increases in Cmax and area under the curve (AUC) for azelastine.
Studies in healthy subjects administered oral doses of azelastine hydrochloride demonstrated linear responses in Cmax and AUC.

Special Populations

Following oral administration, pharmacokinetic parameters were not influenced by age, gender, or hepatic impairment. Based on oral, single-dose studies, renal insufficiency (creatine clearance <50 mL/min) resulted in a 70–75% higher Cmax and AUC compared to normal subjects. Time to maximum concentration was unchanged.
Oral azelastine has been safely administered to over 1400 asthmatic subjects, supporting the safety of administering Astelin® Nasal Spray to allergic rhinitis patients with asthma.

Pharmacodynamics

In a placebo-controlled study (95 subjects with allergic rhinitis), there was no evidence of an effect of Astelin® Nasal Spray (2 sprays per nostril twice daily for 56 days) on car-

Continued on next page

diac repolarization as represented by the corrected QT interval (QTc) of the electrocardiogram. At higher oral exposures (≥4 mg twice daily), a nonclinically significant mean change in the QTc (3–7 millisecond increase) was observed. Interaction studies investigating the cardiac repolarization effects of concomitantly administered oral azelastine hydrochloride and erythromycin or ketoconazole were conducted. Oral erythromycin had no effect on azelastine pharmacokinetics or QTc based on analysis of serial electrocardiograms. Ketoconazole interfered with the measurement of azelastine plasma levels; however, no effects on QTc were observed (see PRECAUTIONS, Drug Interactions).

Clinical Trials

U.S. placebo-controlled clinical trials of Astelin® Nasal Spray included 322 patients with seasonal allergic rhinitis who received two sprays per nostril twice a day for up to 4 weeks. These trials included 55 pediatric patients ages 12 to 16 years. Astelin® Nasal Spray significantly improved a complex of symptoms, which included rhinorrhea, sneezing, and nasal pruritis.

In dose-ranging trials, Astelin® Nasal Spray administration resulted in a decrease in symptoms, which reached statistical significance from saline placebo within 3 hours after initial dosing and persisted over the 12-hour dosing interval. There were no findings on nasal examination in an 8-week study that suggested any adverse effect of azelastine on the nasal mucosa.

INDICATIONS AND USAGE

Astelin® Nasal Spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis such as rhinorrhea, sneezing, and nasal pruritus in adults and children 12 years and older.

CONTRAINDICATIONS

Astelin® Nasal Spray is contraindicated in patients with a known hypersensitivity to azelastine hydrochloride or any of its components.

PRECAUTIONS

Activities Requiring Mental Alertness: In clinical trials, the occurrence of somnolence has been reported in some patients taking Astelin® Nasal Spray; due caution should therefore be exercised when driving a car or operating potentially dangerous machinery. Concurrent use of Astelin® Nasal Spray with alcohol or other CNS depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur.

Information for Patients: Patients should be instructed to use Astelin® Nasal Spray only as prescribed. For the proper use of the nasal spray and to attain maximum improvement, the patient should read and follow carefully the accompanying patient instructions. Patients should be instructed to prime the delivery system before initial use and after storage for 3 or more days (see PATIENT INSTRUCTIONS FOR USE). Patients should also be instructed to store the bottle upright at room temperature with the pump tightly closed and out of the reach of children. In case of accidental ingestion by a young child, seek professional assistance or contact a poison control center immediately.

Patients should be advised against the concurrent use of Astelin® Nasal Spray with other antihistamines without consulting a physician. Patients who are, or may become, pregnant should be told that this product should be used in pregnancy or during lactation only if the potential benefit justifies the potential risks to the fetus or nursing infant.

Patients should be advised to assess their individual responses to Astelin® Nasal Spray before engaging in any activity requiring mental alertness, such as driving a car or operating machinery. Patients should be advised that the concurrent use of Astelin® Nasal Spray with alcohol or other CNS depressants may lead to additional reductions in alertness and impairment of CNS performance and should be avoided (see Drug Interactions).

Drug Interactions: Concurrent use of Astelin® Nasal Spray with alcohol or other CNS depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur.

Cimetidine (400 mg twice daily) increased the mean Cmax and AUC of orally administered azelastine hydrochloride (4 mg twice daily) by approximately 65%. Ranitidine hydrochloride (150 mg twice daily) had no effect on azelastine pharmacokinetics.

Interaction studies investigating the cardiac effects, as measured by the corrected QT interval (QTc), of concomitantly administered oral azelastine hydrochloride and erythromycin or ketoconazole were conducted. Oral erythromycin (500 mg three times daily for seven days) had no effect on azelastine pharmacokinetics or QTc based on analyses of serial electrocardiograms. Ketoconazole (200 mg twice daily for seven days) interfered with the measurement of azelastine plasma concentrations; however, no effects on QTc were observed.

No significant pharmacokinetic interaction was observed with the coadministration of an oral 4 mg dose of azelastine hydrochloride twice daily and theophylline 300 mg or 400 mg twice daily.

Geriatric Use: U.S. placebo-controlled clinical trials included 11 patients above the age of 60 years who were treated with Astelin® Nasal Spray. While this number is very small and no substantial conclusions can be drawn, the adverse events in this group were similar to patients under age 60 years.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity studies in rats and mice with oral azelastine hydrochloride for 24 months at doses up to 30 mg/kg/day and 25 mg/kg/day, respectively (240 and 100 times the maximum recommended human daily intranasal dose on a mg/m^2 basis), revealed no evidence of carcinogenicity.

Azelastine hydrochloride showed no genotoxic effects in the Ames test, DNA repair test, mouse lymphoma forward mutation assay, mouse micronucleus test, or chromosomal aberration test in rat bone marrow.

Reproduction and fertility studies in rats showed no effects on male or female fertility at oral doses of up to 30 mg/kg/day (240 times the maximum recommended human daily intranasal dose on a mg/m^2 basis). At 68.6 mg/kg/day (550 times the maximum recommended human daily intranasal dose on a mg/m^2 basis), the duration of estrous cycles was prolonged and copulatory activity and the number of pregnancies were decreased. The numbers of corpora lutea and implantations were decreased; however, the implantation ratio was not affected.

Pregnancy Category C: Azelastine hydrochloride has been shown to be embryotoxic, fetotoxic, and teratogenic (external and skeletal abnormalities) in mice at an oral dose of 68.6 mg/kg/day (280 times the maximum recommended human daily intranasal dose on a mg/m^2 basis).

At an oral dose of 30 mg/kg/day (240 times the maximum recommended human daily intranasal dose on a mg/m^2 basis), delayed ossification (undeveloped metacarpus), and the incidence of 14th rib were increased in rats. At 68.6 mg/kg/day (550 times the maximum recommended human daily intranasal dose on a mg/m^2 basis) azelastine hydrochloride caused abortion and fetotoxic effects in rats.

The relevance to humans of these skeletal findings noted at only high drug exposure levels is unknown.

There are no adequate and well-controlled clinical studies in pregnant women. Astelin® Nasal Spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether azelastine hydrochloride is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Astelin® Nasal Spray is administered to a nursing woman.

Pediatric Use: Safety and efficacy of Astelin® Nasal Spray in pediatric patients below the age of 12 years have not been established.

ADVERSE REACTIONS

Adverse experience information for Astelin® Nasal Spray is derived from six well-controlled, 2-day to 8-week clinical studies which included 391 patients who received Astelin® Nasal Spray at a dose of 2 sprays per nostril twice daily. In placebo-controlled efficacy trials, the incidence of discontinuation due to adverse reactions in patients receiving Astelin® Nasal Spray was not significantly different from vehicle placebo (2.2% vs 2.8%, respectively).

In these clinical studies, adverse events that occurred statistically significantly more often in patients treated with Astelin® Nasal Spray versus vehicle placebo included bitter taste (19.7% vs 0.6%), somnolence (11.5% vs 5.4%), weight increase (2.0% vs 0%), and myalgia (1.5% vs 0%).

The following adverse events were reported with frequencies ≥2% in the Astelin® Nasal Spray treatment group and more frequently than placebo in short-term (≤2 days) and long-term (2–8 weeks) clinical trials.

ADVERSE EVENT	Astelin® Nasal Spray n=391	Vehicle Placebo n=353
Bitter Taste*	19.7	0.6
Headache	14.8	12.7
Somnolence*	11.5	5.4
Nasal Burning	4.1	1.7
Pharyngitis	3.8	2.8
Dry Mouth	2.8	1.7
Paroxysmal Sneezing	3.1	1.1
Nausea	2.8	1.1
Rhinitis	2.3	1.4
Fatigue	2.3	1.4
Dizziness	2.0	1.4
Epistaxis	2.0	1.4
Weight Increase*	2.0	0.0

*$P<0.05$, Fisher's Exact Test (two-tailed)

The following events were observed infrequently (<2% and exceeding placebo incidence) in patients who received Astelin® Nasal Spray (2 sprays/nostril twice daily) in U.S. clinical trials.

Cardiovascular: flushing, hypertension, tachycardia.

Dermatological: contact dermatitis, eczema, hair and follicle infection, furunculosis.

Digestive: constipation, gastroenteritis, glossitis, ulcerative stomatitis, vomiting, increased SGPT, aphthous stomatitis.

Metabolic and Nutritional: increased appetite.

Musculoskeletal: myalgia, temporomandibular dislocation.

Neurological: hyperkinesia, hypoesthesia, vertigo.

Psychological: anxiety, depersonalization, depression, nervousness, sleep disorder, thinking abnormal.

Respiratory: bronchospasm, coughing, throat burning, laryngitis.

Special Senses: conjunctivitis, eye abnormality, eye pain, watery eyes, taste loss.

Urogenital: albuminuria, amenorrhea, breast pain, hematuria, increased urinary frequency.

Whole Body: allergic reaction, back pain, herpes simplex, viral infection, malaise, pain in extremities, abdominal pain.

In controlled trials involving nasal and oral azelastine hydrochloride formulations, there were infrequent occurrences of hepatic transaminase elevations. The clinical relevance of these reports has not been established.

In addition, the following spontaneous adverse events have been reported during the marketing of Astelin® Nasal Spray and causal relationship with the drug is unknown: anaphylactoid reaction, application site irritation, chest pain, nasal congestion, confusion, diarrhea, dyspnea, facial edema, involuntary muscle contractions, paresthesia, parosmia, pruritus, rash, tolerance, urinary retention, vision abnormal, and xerophthalmia.

OVERDOSAGE

There have been no reported overdosages with Astelin® Nasal Spray. Acute overdosage by adults with this dosage form is unlikely to result in clinically significant adverse events, other than increased somnolence, since one bottle of Astelin® Nasal Spray contains 17 mg of azelastine hydrochloride. Clinical studies in adults with single doses of the oral formulation of azelastine hydrochloride (up to 16 mg) have not resulted in increased incidence of serious adverse events. General supportive measures should be employed if overdosage occurs. There is no known antidote to Astelin® Nasal Spray. Oral ingestion of antihistamines has the potential to cause serious adverse effects in young children. Accordingly, Astelin® Nasal Spray should be kept out of the reach of children. Oral doses greater than 120 mg/kg (480 times the maximum recommended human daily intranasal dose on a mg/m^2 basis) produced significant mortality in mice. Responses seen prior to mortality were tremor, convulsions, decreased muscle tone, and salivation. Single doses as high as 10 mg/kg (270 times the maximum recommended human daily intranasal dose on a mg/m^2 basis) were well tolerated in dogs, but single doses of 20 mg/kg were lethal.

DOSAGE AND ADMINISTRATION

The recommended dose of Astelin® Nasal Spray in adults and children 12 years and older is two sprays per nostril twice daily. Before initial use, the screw cap on the bottle should be replaced with the pump unit and the delivery system should be primed with 4 sprays or until a fine mist appears. When 3 or more days have elapsed since the last use, the pump should be reprimed with 2 sprays or until a fine mist appears.

CAUTION: Avoid spraying in the eyes.

Directions for Use: Illustrated patient instructions for proper use accompany each package of Astelin® Nasal Spray.

HOW SUPPLIED

Astelin® (azelastine hydrochloride) Nasal Spray, 137 mcg, (NDC 0037-0241-10) is supplied as a package containing a total of 200 metered sprays in two high-density polyethylene (HDPE) bottles fitted with screw caps. A separate metered-dose spray pump unit and a leaflet of patient instructions are also provided. The spray pump unit is packaged in a polyethylene wrapper and consists of a nasal spray pump fitted with a blue safety clip and a blue plastic dust cover. Each Astelin® (azelastine hydrochloride) Nasal Spray, 137 mcg, bottle contains 17 mg (1 mg/mL) of azelastine hydrochloride to be used with the supplied metered-dose spray pump unit. Each bottle can deliver 100 metered sprays. Each spray delivers a mean of 0.137 mL solution containing 137 mcg of azelastine hydrochloride.

ATTENTION: The imprinted expiration date applies to the product in the bottles with screw caps. After the spray pump is inserted into the first bottle of the dispensing package, both bottles of product should be discarded after 3 months, not to exceed the expiration date imprinted on the label.

Storage: Store at controlled room temperature 20°–25°C (68°–77°F). Protect from freezing.

Manufactured by
Wallace Laboratories
Division of Carter-Wallace, Inc.
Cranbury, NJ 08512-0181 for
Wallace Laboratories/ASTA Medica LLC

IN-023S3-08A Rev. 1/99

Shown in Product Identification Guide, page 341

DEPEN®
(penicillamine tablets, USP)
Titratable Tablets

℞

Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special