These highlights do not include all the information needed to use PATANASE® Nasal Spray safely and effectively. See full prescribing information for PATANASE Nasal Spray.

PATANASE (olopatadine hydrochloride) Nasal Spray

Initial U.S. Approval: 1996

----------INDICATIONS AND USAGE----------
PATANASE Nasal Spray is an H_1 receptor antagonist indicated for the relief of the symptoms of seasonal allergic rhinitis in adults and children 6 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
For intranasal use only.
Recommended dosages:

- Adults and adolescents ≥ 12years: Two sprays per nostril (665 mcg per spray) twice daily (2.1)
- Children 6 to 11 years: One spray per nostril (665 mcg per spray) twice daily (2.2).

Priming Information: Prime PATANASE Nasal Spray before initial use and when PATANASE Nasal Spray has not been used for more than 7 days (2.3).

---------DOSAGE FORMS AND STRENGTHS----------
Nasal spray 0.6%: 665 mcg of olopatadine hydrochloride in each 100- microliter spray. (3) Supplied as a 30.5 g bottle containing 240 sprays.

----------CONTRAINDICATIONS----------
None.

--------WARNINGS AND PRECAUTIONS-------

- Epistaxis, nasal ulceration, and nasal septal perforation. Monitor patients periodically for signs of adverse effects on the nasal mucosa. Discontinue if ulcerations or perforations occur. Avoid use in patients with nasal disease other than allergic rhinitis (5.1).
- Avoid engaging in hazardous occupations requiring complete mental alertness and coordination such as driving or operating machinery when taking PATANASE Nasal Spray (5.2).
- Avoid concurrent use of alcohol or other central nervous system depressants with PATANASE Nasal Spray (5.2).

----------ADVERSE REACTIONS----------
The most common (>1%) adverse reactions included bitter taste, headache, epistaxis, pharyngolaryngeal pain, post-nasal drip, cough, and urinary tract infection in patients 12 years of age and older and epistaxis, headache, upper respiratory tract infection, bitter taste, pyrexia, and rash in patients 6 to 11 years of age (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc. at 1-800-757-9195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: February 2012

FULL PRESCRIBING INFORMATION*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PATANASE Nasal Spray is an H_1 receptor antagonist indicated for the relief of the symptoms of seasonal allergic rhinitis in adults and children 6 years of age and older.

2 DOSAGE AND ADMINISTRATION

Administer PATANASE Nasal Spray by the intranasal route only.

2.1 Adults and Adolescents 12 years of age and older: The recommended dosage is two sprays per nostril twice daily.

2.2 Children 6 to 11 years of age: The recommended dosage is one spray per nostril twice daily.

2.3 Administration Information
Priming: Before initial use, prime PATANASE Nasal Spray by releasing 5 sprays or until a fine mist appears. When PATANASE Nasal Spray has not been used for more than 7 days, re-prime by releasing 2 sprays. Avoid spraying PATANASE Nasal Spray into the eyes.

3 DOSAGE FORMS AND STRENGTHS

PATANASE Nasal Spray is a nasal spray solution supplied in a white plastic bottle with a metered-dose manual spray pump, a white nasal applicator, and a blue overcap. Each spray (100 microliters) delivers 665 mcg of olopatadine hydrochloride.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Local Nasal Effects
Epistaxis and Nasal Ulceration: In placebo (vehicle nasal spray)-controlled clinical trials of 2 weeks to 12 months duration, epistaxis and nasal ulcerations were reported [*see Adverse Reactions (6)*].

Nasal Septal Perforation:
Three placebo (vehicle nasal spray)-controlled long term (12 months) safety trials were conducted. In the first safety trial, patients were treated with an investigational formulation of PATANASE Nasal Spray containing povidone (not the commercially marketed formulation) or a vehicle nasal spray containing povidone. Nasal septal perforations were reported in one patient treated with the investigational formulation of PATANASE Nasal Spray and 2 patients treated with the vehicle nasal spray. In the second safety trial with PATANASE Nasal Spray, which does not contain povidone, there were no reports of nasal septal perforation. In the third safety trial, one patient exposed to the 3.7 pH vehicle nasal spray (containing no povidone) reported a nasal septal perforation [*see Adverse Reactions (6)*].

Before starting PATANASE Nasal Spray, conduct a nasal examination to ensure that patients are free of nasal disease other than allergic rhinitis. Perform nasal examinations periodically for signs of adverse effects on the nasal mucosa and consider stopping PATANASE Nasal Spray if patients develop nasal ulcerations.

5.2 Activities Requiring Mental Alertness
In clinical trials, the occurrence of somnolence has been reported in some patients taking PATANASE Nasal Spray [*see Adverse Reactions (6)*]. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness and motor coordination such as driving or operating machinery after administration of PATANASE Nasal Spray. Concurrent use of PATANASE Nasal Spray with alcohol or other central nervous system depressants should be avoided because additional reductions in alertness and additional impairment of central nervous system performance may occur.

6 ADVERSE REACTIONS

The most clinically significant adverse reactions described in other sections of labeling include;

- Epistaxis, Nasal Ulceration, and Nasal Septal Perforation [*see Warnings and Precautions (5.1)*]
- Somnolence [*see Warnings and Precautions (5.2)*]

6.1 Clinical Trials Experience
The safety data described below reflect exposure to PATANASE Nasal Spray in 2,770 patients with seasonal or perennial allergic rhinitis in 10 controlled clinical trials of 2 weeks to 12 months duration.

The safety data from adults and adolescents are based upon 6 placebo (3.7 pH vehicle nasal spray or 7.0 pH vehicle nasal spray)-controlled clinical trials in which 1,834 patients with seasonal or perennial allergic rhinitis (652 males and 1,182 females) 12 years of age and older were treated with PATANASE Nasal Spray two sprays per nostril twice daily. There were 1,180 patients (PATANASE Nasal Spray, 587; vehicle nasal spray, 593) that participated in 3 efficacy and safety trials of 2 weeks duration. There were 2,840 patients (PATANASE Nasal Spray, 1,247; 3.7 pH vehicle nasal spray, 1,251; 7.0 pH vehicle nasal spray, 342) that participated in 3 long-term clinical trials of 1 year duration. The racial distribution of adult and adolescent patients receiving PATANASE Nasal Spray was 77% white, 9% black, and 14% other. The incidence of discontinuation due to adverse reactions in these controlled clinical trials was comparable for PATANASE Nasal Spray and vehicle nasal spray. Overall, 4.7% of the 1,834 adult and adolescent patients across all 6 studies treated with PATANASE Nasal Spray, 3.5% of the 1,844 patients treated with 3.7 pH vehicle nasal spray discontinued due to adverse reactions, and 2.9% of the 342 patients treated with 7.0 pH vehicle nasal spray discontinued due to adverse reactions.

The safety data from pediatric patients 6-11 years of age are based upon 3 clinical trials in which 870 children with seasonal allergic rhinitis (376 females and 494 males) were treated with PATANASE Nasal Spray 1 or 2 sprays per nostril twice daily for 2 weeks. The racial distribution of pediatric patients receiving PATANASE Nasal Spray was 68.6% white, 16.6% black, and 14.8% other. The incidence of discontinuation due to adverse reactions in these controlled clinical trials was comparable for PATANASE Nasal Spray and vehicle nasal spray. Overall, 1.4% of the 870 pediatric patients across all 3 studies treated with PATANASE Nasal Spray and 1.3% of the 872 pediatric patients treated with vehicle nasal spray discontinued due to adverse reactions.

Safety information for pediatric patients 2 to 5 years of age is obtained from one vehicle-controlled study of 2 weeks duration [*See Pediatric Use (8.4)*].

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adults and Adolescents 12 Years of Age and Older in Short-Term (2-week) Trials:
There were 1,180 patients 12 years of age and older (PATANASE Nasal Spray, 587; vehicle nasal spray, 593) that participated in 3 efficacy and safety trials of 2 weeks duration. Table 1 presents the most common adverse reactions (0.9% or greater in patients treated with PATANASE Nasal Spray) that occurred more frequently in patients treated with PATANASE Nasal Spray compared with vehicle nasal spray in the 3 clinical trials of 2 weeks duration.

Table 1: Adverse Reactions Occurring at an Incidence of 0.9% or Greater in Controlled Clinical Trials of 2 Weeks Duration with PATANASE Nasal Spray in Adolescent and Adult Patients 12 Years of Age and Older with Seasonal Allergic Rhinitis

	Adult and Adolescent Patients 12 Years and Older	
Adverse Reaction	**PATANASE Nasal Spray N = 587**	**Vehicle Nasal Spray N = 593**
Bitter taste	75 (12.8%)	5 (0.8%)
Headache	26 (4.4%)	24 (4.0%)
Epistaxis	19 (3.2%)	10 (1.7%)
Pharyngolaryngeal Pain	13 (2.2%)	8 (1.3%)
Post-nasal drip	9 (1.5%)	5 (0.8%)
Cough	8 (1.4%)	3 (0.5%)
Urinary tract infection	7 (1.2%)	3 (0.5%)
CPK elevation	5 (0.9%)	2 (0.3%)

Dry mouth	5 (0.9%)	1 (0.2%)
Fatigue	5 (0.9%)	4 (0.7%)
Influenza	5 (0.9%)	1 (0.2%)
Nasopharyngitis	5 (0.9%)	4 (0.7%)
Somnolence	5 (0.9%)	2 (0.3%)
Throat irritation	5 (0.9%)	0 (0.0%)

There were no differences in the incidence of adverse reactions based on gender or race. Clinical trials did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger subjects.

Pediatric Patients 6 to 11 Years of Age: There were 1,742 pediatric patients 6 to 11 years of age (Olopatadine nasal spray, 870; vehicle nasal spray, 872) with seasonal allergic rhinitis that participated in 3 clinical trials of 2 weeks duration. Two of the studies used the investigational formulation of olopatadine nasal spray, and one of the studies used PATANASE Nasal Spray. One study evaluated the safety of PATANASE Nasal Spray at doses of 1 and 2 sprays per nostril twice daily in 1188 patients, in which 298 were exposed to PATANASE 1 spray, 296 were exposed to PATANASE 2 sprays, 297 were exposed to vehicle 1 spray, and 297 were exposed to vehicle 2 sprays twice daily for 2 weeks. Table 2 presents the most common adverse reactions (greater than 1.0% in pediatric patients 6-11 years of age treated with PATANASE Nasal Spray 1 spray/nostril) that occurred more frequently with PATANASE Nasal Spray compared with vehicle nasal spray.

Table 2. Adverse Reactions Occurring at an Incidence of Greater than 1.0% in a Controlled Clinical Trial of 2 Weeks Duration with PATANASE Nasal Spray in Pediatric Patients 6-11 Years of Age With Seasonal Allergic Rhinitis

	Pediatric Patients 6 to 11 Years of Age	
Adverse Reaction	**PATANASE Nasal Spray 1 spray per nostril N = 298**	**Vehicle Nasal Spray 1 spray per nostril N = 297**
Epistaxis	17 (5.7%)	11 (3.7%)
Headache	13 (4.4%)	11 (3.7%)
Upper respiratory tract infection	8 (2.6%)	0
Bitter taste	3 (1.0%)	0
Pyrexia	4 (1.3%)	3 (1.0%)
Rash	4 (1.3%)	0

There were no differences in the incidence of adverse reactions based on gender, race, or ethnicity.

Pediatric Patients 2 to 5 Years of Age: The safety of PATANASE Nasal Spray at a dose of 1 spray per nostril twice daily was evaluated in one 2-week vehicle-controlled study in 132 patients (PATANASE Nasal Spray, 66; vehicle nasal spray. 66) 2 to 5 years of age with allergic rhinitis [*see Pediatric Use (8.4)*].

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.