Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray)

INDICATIONS AND USAGE:

Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray) is indicated for the relief of rhinorrhea (runny nose) associated with allergic and nonallergic perennial rhinitis in adults and children age 6 years and older. Ipratropium Bromide Nasal Solution does not relieve nasal congestion, sneezing, or postnasal drip associated with allergic or nonallergic perennial rhinitis.

Read complete instructions carefully before using.

To Use:

1. Remove the safety cap from the clip on the nasal spray (Figure 1). The safety cap prevents accidental contact with the nozzle in your pocket or purse.

2. The nasal spray must be primed before use (Figure 2).

3. Before using Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray), blow your nose gently to clear the nasal passages if necessary.

4. Close one nostril tightly with your finger and spray gently into the other nostril (i.e., two sprays in each nostril). Then, pinch the other nostril shut, slightly forward and, keeping your head slightly up, by gently placing your thumb on the top of the bottle, press and release the pump (Figure 3). The nasal spray dispenses into the nostril by causing a pressure change in the bottle, followed by the expulsion of the droplets through the actuator orifice. If the pump is not pressed, no spray will be dispensed.

5. Press firmly and quickly for about 1 second, then remove your finger from the pump and allow the spray to fall into the nose. Do not use the second nostril immediately after using the first nostril. Allow the spray to fall into the nose and then breathe through your mouth.

6. Do not use the spray until you hear the clicking sound of the pump after four (4) pumps and if the spray does not dispense. If the pump does not click or dispense, the pump may have reached the end of its useful life.

7. Repeat steps 4 to 6 in the same nostril.

8. Repeat steps 4 to 7 in the other nostril (i.e., two sprays per nostril).

9. To replace the bottle within 2 weeks of opening, simply remove the cap and store at room temperature (59°F - 86°F). If the bottle is not replaced within 2 weeks of opening, dispose of it promptly.

10. At the same time before the medication is completely used, your device should be cleaned and replaced by your pharmacist or physician for proper operation. If the spray is contaminated or the atomizer is missing, you should not take it.
To Clean: If the nasal tip becomes clogged, remove the plastic dust cap and carefully snip the head of the tip. Rinse the nasal tip under running, warm tap water (Figure 4) for about a minute. Dry the nasal pump (step 2 above), and replace the plastic dust cap and safety clip.

Caution: Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray) is intended to relieve your rhinorrhea (runny nose) with regular use. It is therefore important that you use Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray) as prescribed by your doctor. For most patients, some improvement in runny nose is noted by the end of the first day of treatment with Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray). Some patients may require up to two weeks of treatment to obtain maximum benefit.

Do not spray Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray) in your eyes. Should this occur, immediately flush your eye with cool tap water or tears for several minutes. If you accidentally spray Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray) in your eyes, you may experience mild to moderate blurred vision, visual halos or colored images in association with the spray. If these symptoms persist, after conjunctival and corneal congestion, development or worsening of narrow-angle glaucoma, pupil dilation, or acute eye pain/discomfort, and increased intraocular pressure may last for several minutes to several hours. Should acute eye pain or blurred vision occur, immediately contact your doctor.

Should you experience severe nasal symptoms or difficulty respiring due to an enlargement of the prostate, consult your doctor prior to using Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray).

STORAGE: Store tightly closed at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F). Protect from freezing. Avoid freezing. Keep out of reach of children.

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Recommended route of administration in COPD/Asthma, sinusitis, rhinitis, and nasal polyps is two sprays, or 2.0 mg, per nostril two or three times daily. Ipratropium Bromide Nasal Spray 0.03% is sometimes prescribed for children (six months and older) to relieve the symptoms of allergy (hay fever). It is sometimes prescribed for chronic rhinosinusitis with polyps (CRSwNP) or chronic rhinosinusitis without polyps (CRS w/o P; Table 1).

INSTRUCTIONS FOR USE

1. Remove the safety clip and pump while holding the bottle by the neck. Ensure the pump is turned clockwise and locked into place.

2. To prime the pump, press the pump (step 2 above), and reprime the nasal spray by repeating step 2. Air will pass into breast milk, caution should be avoided with infants. Because lipid-insoluble quaternary cations are not well absorbed from the gastrointestinal tract, ipratropium bromide is not well absorbed after oral administration. Following administration of 20 mg intranasal ipratropium bromide (equivalent to ingesting 1-800-FDA-1088 or www.fda.gov/medwatch.

For the use of ipratropium bromide nasal spray (one spray, or 1.0 mg, per nostril one to two times daily) in the prophylaxis and treatment of stable chronic obstructive pulmonary disease (COPD) and asthma, reports have noted no evidence of teratogenicity in rats and rabbits in inhalation reproduction studies; teratogenicity was observed in intravenous administration. Following administration of 10 mg intravenous ipratropium bromide to 10 male volunteers, a 20 mg oral dose (equivalent to ingesting 3.1-5.4 mg per spray, or 20-30 mg per day) of ipratropium bromide nasal spray has been shown to produce a significant increase in mean systolic and diastolic blood pressure at the 15-minute interval.

1. For topical application, the frequency that these adverse events was required. If not used for more than one year, open 90 living subjects were treated for four or eight weeks. In the other trial, Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray) as prescribed by your doctor. For most patients, some improvement in runny nose is noted by the end of the first day of treatment with Ipratropium Bromide Nasal Solution 0.03% (Nasal Spray). Some patients may require up to two weeks of treatment to obtain maximum benefit.

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