**Package leaflet: Information for the user**

**Ipratropium Bromide 21 micrograms per metered dose nasal spray, solution**
Ipratropium bromide

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Ipratropium Bromide is and what it is used for
2. What you need to know before you use Ipratropium Bromide
3. How to use Ipratropium Bromide
4. Possible side effects
5. How to store Ipratropium Bromide
6. Contents of the pack and other information

## 1. What Ipratropium Bromide is and what it is used for

The name of your medicine is Ipratropium Bromide 21 micrograms per metered dose nasal spray solution (called Ipratropium Bromide in this leaflet). It is a solution that you spray into your nose.

Ipratropium Bromide contains a medicine called ipratropium bromide. This belongs to a group of medicines called ‘anticholinergics’. It is used to help stop a runny nose caused by Rhinitis. Rhinitis is an inflammation of the nose which could be because of an allergy (such as hay fever) or other reasons.

## 2. What you need to know before you use Ipratropium Bromide

**Do not use Ipratropium Bromide if:**
- You are allergic (hypersensitive) to ipratropium bromide or any of the other ingredients of this medicine (listed in section 6 below).
- You are allergic (hypersensitive) to medicines that are similar to Ipratropium Bromide, such as atropine.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Ipratropium Bromide.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using your medicine if:
- You have cystic fibrosis
- You have glaucoma or any other eye problems
- You are a man who has prostate problems
- You have problems passing water (urine)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ipratropium Bromide.

- Close your eyes during the application of Ipratropium Bromide in the nose. Do not spray in or around your eyes. If Ipratropium Bromide gets into the eyes, rinse immediately with cold water. After that, you may experience vision problems and increased sensitivity to light for a few hours.

**Other medicines and Ipratropium Bromide**
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Ipratropium Bromide can affect the way some other medicines work. Also, some other medicines can affect the way Ipratropium Bromide works.

There are no known interactions with antihistamines, decongestants or intranasal corticosteroids for nasal use.
- There is a risk of an increase in adverse reactions, if used concomitantly with other anticholinergic medications (oral or inhaled).
- There is also a risk of interaction with salbutamol (contained in some medications used to treat asthma).

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**
You may feel dizzy, or have difficulty in focusing, or blurred vision while taking Ipratropium Bromide. If this happens do not drive or use any tools or machines.

**Ipratropium Bromide contains benzalkonium chloride (preservative).**
Ipratropium Bromide contains 17.5 mcg benzalkonium chloride in each spray which is equivalent to 0.25 mg/ml.
Benzalkonium chloride is an irritant to the skin and may cause skin reactions. Benzalkonium chloride may also cause irritation or swelling inside the nose, especially if used for a long time.

## 3. How to use Ipratropium Bromide
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The recommended dose is:**

**Adults**
- Two sprays in each nostril
- Two to three times each day.

**Use in children under 12 years of age**
- Ipratropium Bromide is not recommended for children under 12 years

**Using this medicine**

1. Remove the cap.

2. The nasal spray pump must be primed before Ipratropium Bromide is used for the first time.

   To prime the pump, hold the bottle with your thumb at the base and your first and middle fingers on the white shoulder area. Point the bottle upright and away from your eyes. Press your thumb

firmly and quickly against the bottle seven times (Fig. 1). The pump is now primed and ready to use.

If it has been more than 24 hours since you used your spray, you will need to prime the pump again before using it. Reprime the pump as before, but this time you will only need to pump the bottle twice.

If you have not used your spray for more than seven days you will need to reprime the pump using the normal seven sprays.

3. Blow your nose to clear your nostrils, if necessary.

4. Close one nostril by gently placing your finger against the side of your nose.

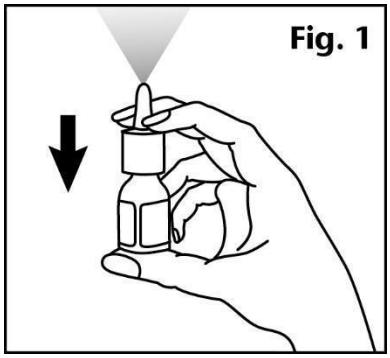
   Tilt your head slightly forward and, keeping the bottle upright, insert the bottle tip into the other nostril. Point the tip toward the back and outer side of your nose (Fig. 2).

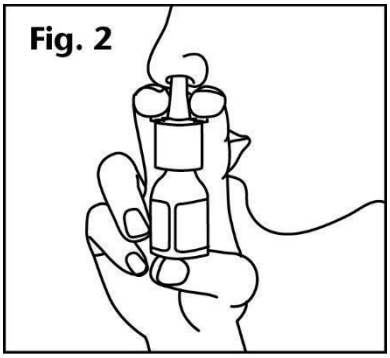
5. Press firmly and quickly upwards with the thumb at the base while holding the white shoulder area between your first and middle fingers. Following each spray, sniff deeply and breathe out through your mouth.

6. After you have finished spraying remove the bottle and tilt your head backwards for a few seconds to let the spray spread over the back of the nose.

7. Repeat step 4 to 6 in the other nostril.

8. Replace the cap.




If the bottle tip becomes clogged, remove the cap. Hold the bottle tip under warm running water for about a minute. Dry the bottle tip, reprime the pump and replace the cap.

If any of the spray accidentally gets into your eyes, wash it out with cold tap water for several minutes. You may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If affected, do not drive or use any tools or machines. If you get problems with your eyes at any other time, talk to your doctor for advice.

**If you use more Ipratropium Bromide than you should**
Do not use more sprays than the doctor has told you. If you use more sprays than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there is no medicine left.

- Symptoms: dry mouth, visual accommodation disturbances and increased heart rhythm may occur.

**If you forget to use Ipratropium Bromide**

- If you forget a dose, use the spray as soon as you remember

- However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines, Ipratropium Bromide can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Stop taking and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment.**
- Allergic reactions – the signs may include itching or nettle rash (affects less than 1 in 1000 people). In severe cases the signs include swelling of your mouth and face, skin rash, sudden difficulties in breathing, and reduction of your blood pressure. Tightening of your throat (affects less than 1 in 100 people)
- Increased heart rate, irregular heart rhythm such as atrial fibrillation or quickening of the heart rate (affects less than 1 in 100 people)
- Palpitations (fast or uneven heart beats) (affects less than 1 in 1000 people)

Stop using this medicine and see your doctor straight away if you have any of these side effects.

**Other side effects include:**

**Common (may affect up to 1 in 10 people)**
- Headache or stuffy nose
- Nasal drying, nasal irritation such as itching or a burning sensation or nosebleeds
- Throat irritation

**Uncommon (may affect up to 1 in 100 people)**
- Skin rash
- Dizziness
- Unexpected tightness of the chest, swelling of the throat, dry throat
- Blurred vision, difficulty focusing, dilated pupils, glaucoma, painful, stinging, red or swelling of the eyes, seeing colours or lights
- Mouth or lip sores
- Problems passing water (urine), especially if you already have problems passing urine
- Feeling sick (nausea), burning sensation, stomach upset or discomfort
- Dry mouth

**Rare (may affect up to 1 in 1,000 people)**
- Itching or nettle rash (urticaria)

If any of the spray accidentally gets into your eyes, wash it out with cold tap water for several minutes. You may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Ipratropium Bromide

Do not freeze.
**Do not drop the bottle.**

Keep this medicine out of the sight and reach of children.

Use this spray within three months of first priming the nasal spray pump. Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Ipratropium Bromide contains**
- Each metered dose contains 21 micrograms of the active ingredient ipratropium bromide (as monohydrate).
- The other ingredients are sodium chloride, benzalkonium chloride, disodium edetate, sodium hydroxide and hydrochloric acid (for pH adjustment), purified water.

**What Ipratropium Bromide looks like and contents of the pack**
Nasal spray solution: Brown glass bottle of 20 ml with a metered nasal spray pump.

One bottle contains 240 doses.

**Marketing Authorisation Holder and Manufacturer**
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