

PACKAGE LEAFLET: INFORMATION FOR THE USER

IPRATROPIUM STERI-NEB 250 MICROGRAMS/ML NEBULISER SOLUTION ipratropium bromide

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Ipratropium Steri-Neb is and what it is used for
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1. WHAT IPRATROPIUM STERI-NEB IS AND WHAT IT IS USED FOR

The name of your medicine is Ipratropium Steri-Neb 250 micrograms/ml Nebuliser solution (called 'Ipratropium Steri-Neb' in the rest of this leaflet). You use it with a device called a 'nebuliser'. This changes your medicine into a mist for you to breathe in.

Ipratropium Steri-Neb contains a medicine called ipratropium bromide. This belongs to a group of medicines called bronchodilators. It is used to make breathing easier for people who have breathing difficulties, such as in chronic asthma or chronic obstructive pulmonary disease (COPD). Ipratropium Steri-Neb can be taken at the same time as medicines called 'beta₂-agonist bronchodilators' such as salbutamol.

Ipratropium Steri-Neb works by opening up your airways.

2. BEFORE YOU USE IPRATROPIUM STERI-NEB

DO NOT use Ipratropium Steri-Neb:

- You are allergic (hypersensitive) to ipratropium bromide or any of the other ingredients listed in section 6 of this leaflet
- You are allergic (hypersensitive) to medicines that are similar to Ipratropium Steri-Neb, 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 Steri-Neb.

Take special care with Ipratropium Steri-Neb

Check with your doctor or pharmacist before using your medicine if:

- you have cystic fibrosis
- you have glaucoma or have been told that you may develop it
- you are a man who has prostate problems
- you have problems passing water (urine)
- you have problems with intestinal blockage

- you have heart disease
- you are pregnant, likely to get pregnant or if you are breast-feeding.

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

Other medicines and Ipratropium Steri-Neb

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Ipratropium Steri-Neb can affect the way some other medicines work. Also some other medicines can affect the way Ipratropium Steri-Neb works.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- Medicines for breathing problems called 'beta-agonists' such as salbutamol
- Medicines for breathing problems called 'xanthine preparations' such as theophylline or aminophylline
- Medicines known as 'anticholinergics' such as atropine.

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

Pregnancy and breast-feeding

- If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before using this medicine.

Driving and using machines

- You may feel dizzy, have difficulty in focusing, dilated pupils or blurred vision while taking Ipratropium Steri-Neb. If this happens do not drive or use any tools or machines.

3. HOW TO USE IPRATROPIUM STERI-NEB

Always use Ipratropium Steri-Neb exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You must only use Ipratropium Steri-Neb in a power-operated nebuliser. The nebuliser turns the solution into a fine mist that you can breathe in. Delivery of the aerosol may be by face mask or "T" piece. Read the manufacturer's instructions and make sure you know how to use the nebuliser before you use your medicine. If anything is unclear after reading this leaflet, ask your doctor or pharmacist.

The usual dose is:

Adults (including the elderly) and children over 12 years:

- The usual dose is 500 micrograms (2 ml of solution) three to four times a day.
- For acute attacks of breathlessness use 500 micrograms (2 ml of solution).
- If breathlessness does not go away or gets worse, consult your doctor.

Children 6-12 yrs:

- The usual dose is 250 micrograms (1 ml of solution) up to a total daily dose of 1 mg (4 ml of solution).
- The time between doses should be decided by your doctor.

Children 0-5 yrs (for treatment of acute asthma only and under medical supervision):

- The usual dose is 125-250 micrograms (0.5-1 ml of solution) up to a total daily dose of 1 mg (4 ml of solution).

- The time between doses should be decided by your doctor but should not be given more frequently than every 6 hours in this age group.

When children are using this medicine they must be supervised by a responsible adult.

Do not swallow or give this medicine by injection.

Do not use your nebuliser to take Ipratropium Steri-Neb and 'disodium cromoglycate inhalation solutions' which have the preservative 'benzalkonium chloride' at the same time.

Do not use more than your doctor has told you

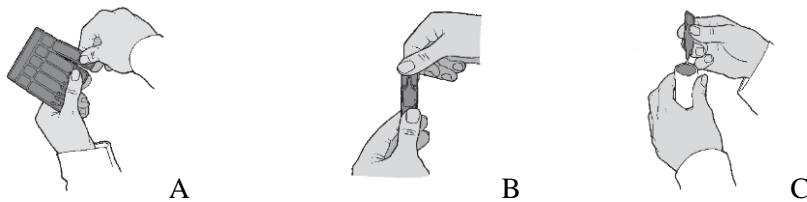
See your doctor straight away if:

- You feel that your medicine is not working as well as usual
- You need to use the nebuliser more than your doctor has recommended

Your doctor may need to check how well your medicine is working. In some cases your doctor may need to change your medicine.

How to use Ipratropium Steri-Neb with your Nebuliser

- Prepare your nebuliser for use according to the manufacturer's instructions.
- Remove a Steri-Neb from the labelled strip by twisting and pulling (diagram A).
- Hold the Steri-Neb upright and twist off the cap (diagram B).
- Squeeze the contents into the reservoir of your nebuliser (diagram C).
- Following the manufacturer's instructions, use your nebuliser.
- After you have used your nebuliser, throw away any solution that is left in the reservoir.
- Clean your nebuliser thoroughly.



Special Precautions for use of Ipratropium Steri-Neb

- DO NOT dilute the solution or mix it with other medicines, unless your doctor tells you to.
- DO NOT swallow the solution or use it in injections.
- DO NOT get the solution or mist in your eyes. It is advisable to administer the inhalation fluid with the use of a mouthpiece. If a nebuliser mask is used, this should fit the face well. If any of the liquid or mist accidentally gets into your eyes 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.

Patients who are at a high risk of increased intraocular pressure (glaucoma) should make sure that they protect their eyes well when using Ipratropium Steri-Neb.

If you use more Ipratropium Steri-Neb than you should

- If you (or someone else) swallow or use a lot of the solution all together, or if you think a child has swallowed or used any of the solution contact your nearest hospital casualty department or your doctor immediately.

In the case of a serious overdose, more rapid breathing, a high fever, restlessness, confusion, and hallucinations can occur as well as a faster heartbeat.

Please take this leaflet, any remaining solution, and the container with you to the hospital, or doctor so that they know which solution has been consumed.

If you forget to use Ipratropium Steri-Neb

- If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

If you stop using Ipratropium Steri-Neb

- DO NOT stop using your medicine without talking to your doctor first even if you feel better.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ipratropium Steri-Neb can cause side effects, although not everybody gets them.

Stop using Ipratropium Steri-Neb and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- If after using Ipratropium Steri-Neb you are wheezy or have other difficulties in breathing, do not use any more (unless you have been told to by your doctor)
- Allergic reactions – the signs may include skin rash and itching (affects less than 1 in 100 people). In severe cases the signs include swelling of your mouth and face, sudden difficulties in breathing and reduction of your blood pressure. Tightening of your throat (affects less than 1 in 100 people)
- Palpitations (fast or uneven heart beats) or quickening of the heart rate (affects less than 1 in 100 people)
- Increased heart rate or irregular heart rhythm such as atrial fibrillation (affects less than 1 in 1,000 people).

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

Other side effects include:**Common** (affects less than 1 in 10 people)

- Headache, dizziness
- Dry mouth, gastrointestinal motility disorder, feeling sick (nausea)
- Cough and throat irritation when you have just used Ipratropium Steri-Neb.

Uncommon (affects less than 1 in 100 people)

- Itching, skin rash
- Unexpected tightness of the chest, swelling of the throat, dry throat
- Blurred vision, dilated pupils, glaucoma, painful, stinging, red or swelling of the eyes, see colours or lights
- Diarrhoea, constipation or being sick
- Mouth or lip sores
- Problems passing water (urine), especially if you already have problems passing urine.

Rare (affects less than 1 in 1,000 people)

- Difficulty focusing
- Nettle rash (urticaria).

Very rare (affects less than 1 in 10,000 people)

- Intestinal blockage.

If any of the liquid or mist accidentally gets into your eyes 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.

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 HPRAs Pharmacovigilance Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IPRATROPIUM STERI-NEB

Keep out of the sight and reach of children.

Do not store above 25°C. Do not refrigerate or freeze.
Keep container in outer carton to protect from light.

For single use only. Use immediately. Discard any unused portion.

Do not use Ipratropium Steri-Neb after the expiry date which is stated on the carton, on the foil laminate pouch and on each Steri-Neb unit after EXP. The expiry date refers to the last day of that month.

Do not use Ipratropium Steri-Neb if you notice the solution is cloudy.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ipratropium Steri-Neb solution contains:

- The active ingredient is ipratropium bromide 250 micrograms/ml.
The 1 ml Steri-Neb contains 250 micrograms of ipratropium bromide.
The 2 ml Steri-Neb contains 500 micrograms of ipratropium bromide
- The other ingredients are sodium chloride, water for injections, and dilute hydrochloric acid to adjust the pH.

What Ipratropium Steri-Neb solution looks like and contents of the pack:

- Each Ipratropium Steri-Neb is a plastic vial containing a clear solution.
- Strips of 5 Steri-Neb are packed into foil laminate pouches, which in turn are packed into boxes containing 20 and 100 (ampoules).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer:

Merckle GmbH, Ludwig-Merckle-Strasse 3,

D-89143 Blaubeuren,
Germany.

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‘Steri-Neb’ is a trademark