

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 or pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

PEE100-04



What is in this leaflet

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

1. What Ipratropium Steri-Neb is and what it is used for

Ipratropium Steri-Neb contains a solution of ipratropium bromide, which is an anticholinergic bronchodilator agent that helps to manage conditions where there is a blockage of the airways. It works by relaxing the smooth muscles in the passage of the lungs. This helps to relieve the narrowing and tightness you feel in your lungs.

Ipratropium Steri-Neb is used to treat breathing problems in people with chest illnesses such as chronic obstructive pulmonary disease (COPD) and asthma.

2. What do you need to know before you use Ipratropium Steri-Neb

Do not use Ipratropium Steri-Neb and talk to your doctor:

- if you are allergic to ipratropium bromide or atropine or any of the other ingredients of this medicine (listed in section 6).

Take special care with and talk to your doctor before you start to use Ipratropium Steri-Neb if you:

- suffer from an eye condition called glaucoma or have been told that you may develop it.
- suffer from an enlarged prostate.
- suffer from cystic fibrosis.
- suffer from problems passing water (urine)
- 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.

Taking or using other medicines

- Ipratropium Steri-Neb can be used in combination with other medicines for the treatment of respiratory conditions such as beta-adrenergic drugs (e.g. salbutamol, formoterol), theophylline, disodium cromoglicate and inhaled corticosteroids (e.g. beclometasone). Talk to your doctor before you start to use Ipratropium Steri-Neb if you

are using any of these medicines, as your dose may need to be adjusted.

- Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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

Driving and using machines

Ipratropium Steri-Neb is not expected to affect your ability to drive or operate machinery.

3. How to use Ipratropium Steri-Neb

Always use Ipratropium Steri-Neb exactly as your doctor has told you. 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.

The usual dose is:

- **Adults including the Elderly**
0.4 to 2.0ml of solution (100 to 500 micrograms) up to four times a day.
- **Children**
0.4 to 2.0ml of solution (100 to 500 micrograms) up to three times a day.

Children under 18 years should only use a nebuliser to take reliever medications under the care of a doctor with expertise in the management of asthma so that deterioration in asthma control can be detected and treated without delay.

Only use the nebuliser recommended by your doctor and supervise your child while they are using the nebuliser.

Seek urgent medical assistance if the nebulised medication is not working, even if there is short-term recovery following use of prescribed nebulised medication.

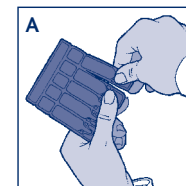
What to do if you think your medicine is not working

- Tell your doctor if your breathing gets worse or your medicine does not provide as much relief from your condition as before. You should NOT change the dose you take, or how often you use your medicine without seeking medical advice.

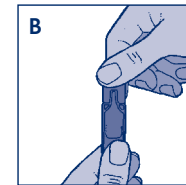
How to use Ipratropium Steri-Neb with your Nebuliser

- 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).

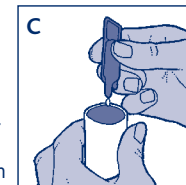


- Hold the Steri-Neb upright and twist off the cap (diagram B).



- 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. There have been rare reports of ocular problems when the spray has entered the eyes. 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 have used a slightly larger dose than usual, you may notice a faster heart beat (palpitations). This usually wears off in a few hours.

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, this medicine can cause side effects, although not everybody gets them.

Most of these are nothing to worry about.

Stop using the solution and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).
- a sudden increase in breathlessness or wheezing, which may be due to paradoxical bronchospasm (narrowing of the air passage or tightening of the chest).

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Stop using the solution and tell your doctor if you suffer from any of the following for more than a few days.

- a dry mouth.
 - constipation and difficulty passing water.
- If you notice any of the following symptoms after the inhalation of Ipratropium Steri-Neb, you should consult your doctor:
- pain in or painfulness of the eyes, blurred vision, coloured rings or images together with red eyes.

The following side effects have been reported at the approximate frequencies shown:

Common side effects that occurred in less than one in ten and more than one in one hundred patients were:

- cough
- sore throat and hoarseness
- Throat irritation
- dry mouth
- nausea
- headache.

Uncommon side effects that occurred in less than one in one hundred but more than one in one thousand patients were:

- palpitations (heart pounding)
- fast heart beat
- hypersensitivity
- Skin rash

- Anaphylactic reaction
- Blurred vision
- Mydriasis
- Intraocular pressure increased
- Glaucoma
- Eye pain
- Halo vision
- Conjunctival hyperaemia
- Corneal oedema
- Gastro-intestinal motility disorder
- Urinary Retention
- Bronchospasm
- Paradoxical bronchospasm
- Laryngospasm
- Pharyngeal oedema
- Dry throat

Rare side effects that occurred in less than one in one thousand but more than one in ten thousand patients included:

- blurred vision
- difficulty in urinating
- Accommodation disorder
- Atrial fibrillation
- Heart rate increased
- Urticaria

Other side effects that have been reported in individual cases include:

- visual disturbances
- dizziness
- stomach disorders
- tightness of the chest causing breathing difficulties.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Steri-Neb

Keep this medicine 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 this medicine after the expiry date which is stated on the carton 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.

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 Steri-Neb solution contains

- The active ingredient is Ipratropium Bromide 250 micrograms/ml.
The 1ml Steri-Neb contains 250 micrograms of ipratropium bromide.
The 2ml 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 (Steri-Neb).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Norton Healthcare Ltd T/A
IVAX Pharmaceuticals UK,
Ridings Point,
Whistler Drive,
Castleford,
West Yorkshire,
WF10 5HX, United Kingdom

Manufacturer

IVAX Pharmaceuticals UK,
Aston Lane North,
Whitehouse Vale Industrial Estate,
Preston Brook, Runcorn,
Cheshire, WA7 3FA, United Kingdom

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'Steri-Neb' is a trademark

Ipratropium Steri-Neb 250 micrograms/ml
Nebuliser Solution
Ipratropium Bromide
Package leaflet: Information for the user

IVAX