In this leaflet

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. Before you use Ipratropium Steri-Neb

DO NOT use Ipratropium Steri-Neb and talk to your doctor if:
- you are allergic to medicines containing ipratropium bromide or atropine or any of the other ingredients listed in section 6 of the leaflet.
- 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
  - suffer from an enlarged prostate.
  - suffer from cystic fibrosis

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, planning to become pregnant or are breast-feeding, 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. 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.

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.

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.

If 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 take 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.

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.
- 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.
- dry mouth.
- feeling sick.
- 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.
- skin rash and other allergic reactions.

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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, or if you feel unwell in any other way, please tell your doctor or pharmacist.

5. How to store

Ipratropium Steri-Neb

**Keep out of the reach and sight 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.

These measures will help to protect the environment.

Keep out of the 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.

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 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-NebS are packed into foil laminate pouches, which in turn are packed into boxes containing 20 and 100 (Steri-NebS).
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Company responsible for manufacture: IVAX Pharmaceuticals UK, Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, Cheshire, WA7 3FA, United Kingdom.