

Package Leaflet: Information for the user

Ipramol Steri-Neb 0.5 mg/2.5 mg per 2.5 ml Nebuliser Solution

ipratropium bromide and salbutamol

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 further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ipramol Steri-Neb is and what it is used for
2. What you need to know before you use Ipramol Steri-Neb
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1. What Ipramol Steri-Neb is and what it is used for

Your medicine is called Ipramol Steri-Neb 0.5 mg/2.5 mg per 2.5 ml Nebuliser Solution. The active ingredients are ipratropium bromide and salbutamol sulfate. Ipratropium bromide and salbutamol both belong to a group of medicines called bronchodilators, which help to improve your breathing by opening up your airways. This is achieved by preventing the contraction of the smooth muscles surrounding the airways, therefore allowing the airways to remain open. Ipratropium bromide acts by blocking the nerve signals that go to the muscles surrounding the airways, and salbutamol acts by stimulating specific receptors in the muscles.

Ipramol Steri-Neb is used to treat breathing problems in people with long-standing breathing difficulties in an illness called ‘chronic obstructive pulmonary disease’ or ‘COPD’. Ipramol Steri-Neb will relieve wheezing, shortness of breath and chest tightness by opening up your airways.

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

Do not use Ipramol Steri-Neb:

- if you are allergic to ipratropium or salbutamol or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to medicines that contain atropine or medicines like atropine
- if you suffer from abnormal heart rhythms including a very fast heart beat (called ‘tachyarrhythmia’)
- if you have an enlarged heart or a condition known as hypertrophic obstructive cardiomyopathy, where the wall between the two sides of the heart becomes thicker and blocks the blood flow.

If you are not sure, talk to your doctor or pharmacist before using Ipramol Steri-Neb.

Warnings and precautions

Talk to your doctor or pharmacist before using Ipramol Steri-Neb:

- if you suffer from or think you may suffer from an eye condition known as glaucoma (increased pressure in the eyes) or if you suffer from any other eye conditions. Your doctor may advise you to protect your eyes when using Ipramol Steri-Neb;
- if you are male and you know that you have an enlarged prostate or if you have problems passing urine (water);
- if you have had a recent heart attack (myocardial infarction); if you have problems with your arteries or get pain in your legs when you walk;
- if you have a history of heart disease, irregular heart rhythm or angina (please tell your doctor before starting this medication);
- if you have diabetes;
- if you have an overactive thyroid gland;
- if you suffer from cystic fibrosis in this situation you may be more likely to suffer from gastrointestinal motility disorders.
- if you have been told that you have a tumour of the adrenal gland called pheochromocytoma.

If any of the following occurs while taking Ipramol Steri-Neb, consult your doctor immediately:

- if you have severe heart disease (e.g. ischaemic heart disease, tachyarrhythmia or severe heart failure) and experience chest pain or other symptoms of worsening heart disease;
- in case of acute dyspnoea (difficulty in breathing) that worsens rapidly.

A condition known as lactic acidosis has been reported in association with high therapeutic doses of salbutamol, mainly in patients being treated for an acute bronchospasm (see section 3 and 4). Increase in lactate levels may lead to shortness of breath and hyperventilation even though there may be improvement in your wheezing. If you feel that your medicine is not working as well as usual and you need to use the nebuliser more than your doctor has recommended, immediately talk to a doctor.

Children and adolescents

Ipramol Steri-Neb is not recommended in children 12 years of age and younger, as safety and efficacy have not been established in this age group.

Other medicines and Ipramol Steri-Neb

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Certain medicines may interact with Ipramol Steri-Neb and may worsen side effects or reduce the effect of Ipramol Steri-Neb. You must always tell your doctor if you are taking any of the following medicines:

- other asthma medicines, including inhalers and tablets for asthma and including treatments known as “relievers” such as salbutamol and “preventers” such as beclometasone dipropionate. These may increase the effect of Ipramol Steri-Neb and increase the severity of side effects;
- beta-blockers i.e. medicines that are commonly used to treat heart conditions such as chest pain that occurs on exertion (called angina pectoris), irregular heartbeats or arrhythmias and high blood pressure (called hypertension). They include drugs such as propranolol. These drugs oppose the ‘airway opening’ effects of Ipramol Steri-Neb;
- certain drugs to treat depression (such as “anti-depressants” are drugs that are prescribed for patients suffering from depression and anxiety). This class of drug includes medicines such as monoamine oxidase inhibitors (e.g. phenelzine) or tricyclic antidepressants (e.g. amitriptyline);
- digoxin (for heart problems) may cause heart rhythm problems when given with Ipramol Steri-Neb;
- diuretics (“water tablets”) and steroid tablets (these are medicines that reduce inflammation such as prednisolone). These drugs may increase risk of low potassium levels;

- anaesthetic agents may increase the susceptibility of the effects of salbutamol on the heart – you will be monitored closely or your doctor might decide to discontinue Ipramol Steri-Neb if you are going to have an operation.

If you are going to have a general anaesthetic in hospital or at the dentist, please tell the anaesthetist what drugs you are taking.

If you have to provide a urine sample as part of a routine sport drug test, tell the person giving the test that you are taking Ipramol Steri-Neb because it contains salbutamol, which may lead to a positive test result.

Ipramol Steri-Neb with food and drink

Food and drink have no influence on Ipramol Steri-Neb.

Pregnancy, breast-feeding and fertility

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

Ipramol Steri-Neb should not be used during pregnancy or breast-feeding unless your doctor decides that the benefits to the mother outweigh the risk to the baby.

Driving and using machines

You may feel dizzy, or have difficulty in focusing or experience blurred vision while taking Ipramol Steri-Neb. If this occurs do not drive or use tools or machines.

3. How to use Ipramol Steri-Neb

Ipramol Steri-Neb is for inhalation use after nebulisation.

Always use Ipramol Steri-Neb exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or nurse if you are not sure.

The recommended dose for adults and children over 12 years of age is the contents of one ampoule, three or four times a day.

Elderly patients should take the usual adult dose.

Ipramol Steri-Neb has not been studied in patients with liver or kidney failure, so it should be used with caution in these patient populations.

Ipramol Steri-Neb is **not** recommended for children under 12 years of age.

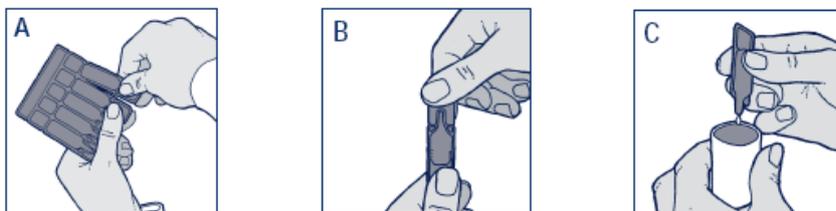
The label will tell you how much to take and how often to take it.

Never use more medicine than your doctor has told you to. Tell your doctor if your breathing problems get worse or your medicine does not provide as much relief from your breathing problems as before or if you are using your blue short-acting “reliever” inhaler more often than is usual for you.

Instructions for Use

- Prepare your nebuliser for use according to the manufacturer’s instructions and advice from your doctor.
- Carefully remove an ampoule from the labelled strip by twisting and pulling. Never use an ampoule that has been opened already or if the solution is discoloured (diagram A).

- Hold the ampoule upright and twist off the cap (diagram B).
- Squeeze the contents into the reservoir of your nebuliser (diagram C).
- Follow the manufacturer's instructions and the advice from your doctor on how to assemble and how to use your nebuliser.
- After you have used your nebuliser, throw away any solution that is left in the reservoir. Any solution left in the ampoule should also be thrown away.
- Clean your nebuliser thoroughly according to the manufacturer's instructions. It is important that the nebuliser is kept clean.



Do not dilute the solution or mix it with other medicines, unless your doctor tells you to.

The single dose ampoules of Ipramol Steri-Neb do not contain preservatives and therefore it is important to use the contents immediately after opening. A new ampoule must be used each time you use Ipramol Steri-Neb in your nebuliser.

Partly used, opened or damaged ampoules should be discarded. You should **never** use an ampoule, which has been opened earlier.

It is important that you follow these instructions in order to avoid any contamination of the nebuliser solution within the ampoules.

Do **not** swallow the solution or use it in injections.

Do **not** allow the solution or mist to enter your eyes.

If you use more Ipramol Steri-Neb than you should

If you have taken a slightly larger dose than usual, you may notice a faster heart beat (palpitations) or tremor. Other symptoms might include chest pain, changes in blood pressure, flushing, restlessness, dizziness, widening of pulse pressures, irregular heartbeat, dry mouth and problems of the eyes to focus things. These effects usually wear off in a few hours. The level of potassium in your blood may fall and the doctor may want to monitor the potassium in your blood by taking a blood test to measure the levels from time to time.

An excess of the acidity in the blood (metabolic acidosis) has also been observed in overdoses. Treatment with sedatives and tranquillisers may be required in cases of overdose. Tell your doctor if you are worried by any of these symptoms or if they persist.

If you have taken more medicine than you should have taken, tell your doctor immediately or go to the nearest hospital. If you need to visit a doctor or need to go into hospital then you should take all of your medicines with you, including any you may have bought without a prescription; these should be in their original packaging if at all possible. Take this leaflet with you to show the doctor.

If you forget to use Ipramol Steri-Neb

If you forget to take a dose at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop using Ipramol Steri-Neb

You should not stop taking Ipramol Steri-Neb without prior discussion with your doctor.

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

4. Possible Side Effects

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

Some of the side-effects may be serious and require medical intervention.

Serious Side Effects

If your asthma or wheezing gets worse immediately after inhaling Ipramol Steri-Neb Nebuliser Solution, or your breathing becomes more difficult and you become short of breath do not take any more Ipramol Steri-Neb but use your short-acting 'reliever' inhaler straight away. You should stop using Ipramol Steri-Neb and should contact your doctor immediately. Your doctor may prescribe alternative treatment for your condition.

If you experience eye pain or eye discomfort, blurred vision or red eyes, or if you see halos or coloured spots then you should contact your doctor straightaway as treatment for these symptoms may be required.

If you think that you may be allergic to Ipramol Steri-Neb Nebuliser Solution or if you think you may be having an allergic reaction to the solution then you should stop using Ipramol Steri-Neb straight away and contact your doctor immediately.

A reduction in the level of potassium (hypokalaemia) in the blood due to the salbutamol component of Ipramol Steri-Neb can occur – and this may cause muscle weakness, twitching or abnormal heart rhythm. This is more likely to happen if you are taking Ipramol Steri-Neb with some other asthma treatments, with inhaled steroids or steroid tablets or with diuretics ("water tablets"). Your doctor may need to take a blood test to measure your potassium levels from time to time.

Occurrence rates for side effects

Uncommon: may affect up to 1 in 100 people

- headaches
- palpitations or fast heart beat
- dryness of mouth
- nausea (feeling sick)
- throat irritation
- cough
- speech difficulties
- dizziness
- increased blood pressure
- restlessness
- tremor

Rare: may affect up to 1 in 1,000 people

- severe allergic reactions (anaphylactic reactions)
- allergic reactions including swelling of the tongue, lips and face
- breathing difficulties and shortness of breath
- sweating
- flushing

- reduced blood pressure
- irregular heart rhythm
- chest pain (due to cardiac problems)
- vomiting (being sick)
- gastro-intestinal motility disturbances,
- diarrhoea, obstipation
- edema of the mouth and throat
- dry throat
- inflammation of the lining of the mouth
- itching
- rashes
- rapid swelling under the skin (angioedema)
- muscular pains, weakness and cramps
- memory disorders
- mental disorders
- anxiety
- hyperactivity in children
- eye pain or other problems with the eyes including disturbed eye accommodation, blurring of vision, excessive dilation of the pupil of the eye and glaucoma (increased pressure in the eyes), red eye, visual halos, corneal edema.
- low potassium levels in your blood
- difficulty in passing urine (water)
- fatigue

Rarely, some people might experience chest pain (due to problems such as angina). Tell your doctor as soon as possible if you develop these symptoms whilst receiving treatment with Ipramol Steri-Neb, but do not stop using this medicine unless told to do so.

The following side effects can also happen but the frequency of these are not known:

A condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath even though there may be improvement in your wheezing, cold feet and hands, irregular heartbeat or thirst.

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 HPRA 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 Ipramol Steri-Neb

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

Do not use Ipramol Steri-Neb after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Keep Ipramol Steri-Neb ampoules in the box they came in. Store in original packaging in order to protect from light. Store below 25°C. Do not freeze.

Do not take this medicine if you notice the solution is discoloured or cloudy.

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

6 Contents of the pack and other information

What Ipramol Steri-Neb contains

- The active substances are: 0.5 milligrams of ipratropium bromide (as the monohydrate) and 2.5 milligrams of salbutamol (as the sulfate);
- The other ingredients are: sodium chloride, water for injections and dilute hydrochloric acid.

What Ipramol Steri-Neb looks like and contents of the pack

Each Ipramol Steri-Neb consists of a plastic ampoule containing a clear solution. Strips of 5 ampoules are packed into foil laminate pouches, which in turn are packed into cardboard cartons containing 5, 10, 15, 20, 25, 30, 40, 50 or 60 ampoules and a 2 x 30 ampoule-pack, then packed into a cardboard carton.

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:

IVAX Pharmaceuticals UK, Preston Brook, Runcorn, Cheshire, WA7 3FA, UK.

Merckle GmbH, Ludwig-Merckle-Str. 3, 89143 Blaubeuren, Germany.

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland	Ipramol Steri-Neb 0.5 mg/2.5 mg per 2.5 ml Nebuliser Solution
The Netherlands	Ipramol 0.5mg / 2.5mg per 2.5 ml Verneveloplossing
Sweden	Ipramol 0.5mg / 2.5mg lösning för nebulisator
United Kingdom (Northern Ireland):	Ipramol Steri-Neb 0.5mg / 2.5mg per 2.5ml Nebuliser Solution
Belgium	Nebu-Iprasal 0,5 mg/2,5 mg verneveloplossing
Germany	Ipramol TEVA 0,5 mg + 2,5 mg /2,5 ml Steri-Neb Lösung für einen Vernebler
Denmark	Ipramol Steri-Neb

Portugal Ipramol 0.5 mg/dose + 2.5 mg/dose Solução para inalação por nebulização

This leaflet was last revised in January 2022.

‘Steri-Neb’ is a trademark

‘Ipramol’ is a registered trademark