

Package leaflet:Information for the user

Sapimol 0.5mg / 2.5mg per 2.5ml Nebuliser Solution

(Ipratropium bromide/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 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.

What is in this leaflet:

1. What [Product name] Nebuliser Solution is and what it is used for
2. What you need to know before you use [Product name] Nebuliser Solution
3. How to use [Product name] Nebuliser Solution
4. Possible side effects
5. How to store [Product name] Nebuliser Solution
6. Content of the pack and other information

1. What [Product name] NEBULISER SOLUTION is and what it is used for

[Product name] Nebuliser Solution belongs to a group of medicines called “bronchodilators” which help to open up the air passages in your lungs so that you can breathe more easily.

[Product name] Nebuliser Solution helps to make breathing easier in patients who have long-standing breathing difficulties.

2. What you need to know before you use [Product name] NEBULISER SOLUTION

Do not use [Product name] Nebuliser Solution:

- If you are allergic (hypersensitive) to ipratropium bromide, salbutamol sulfate, atropine or any of the other ingredients of this medicine (listed in section 6)
- If you have a heart condition called cardiomyopathy (this is when your heart does not work properly due to inflammation of the heart muscles)
- If you have a fast and irregular heartbeat (known as tachyarrhythmia)

Warnings and precaution

Talk to your doctor or pharmacist before using [Product name]:

- If you are pregnant, thinking of becoming pregnant or if you are breast-feeding
- If you have diabetes
- If you have a heart condition, a history of heart disease or have recently had a heart attack
- If you have high blood pressure, an irregular heart rhythm or angina
- If you have an overactive thyroid gland
- If you suffer from cystic fibrosis
- If you have a condition which makes passing urine difficult

- If you suffer from glaucoma (excessive pressure inside your eyes) or you are at risk of suffering from it
- If you have or have had problems with your liver or kidneys
- If you have ever been told that you suffer from pheochromocytoma. This is a rare tumour which produces chemicals that can cause restlessness, high blood pressure and your heart to beat faster.

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.

Good oral hygiene and regular dental check-ups are recommended, particularly in children.

Other medicines and [Product name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any of the following as they may interact with [Product name]:

- Steroids including prednisolone
- Medicines called xanthines such as theophylline
- Medicines called beta-blockers such as propranolol or timolol, as these can reduce the effectiveness of your medicine
- Diuretic medicines (commonly known as ‘water tablets’) including non-sparing potassium diuretics such as furosemide or indapamide
- Digoxin, which is used in the treatment of heart failure
- Other medicines which can help you breathe such as terbutaline
- Anticholinergic medicines (which can be used to treat asthma, irritable bowel syndrome, Parkinson’s disease and incontinence)
- Certain medicines to treat depression (known as ‘monoamine oxidase inhibitors’ and ‘tricyclic antidepressants’).

Some anaesthetic gases may interact with your medicine. If you are to undergo any surgery, you should tell the anaesthetist or doctor that you are taking [Product name] Nebuliser Solution.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. If you are breast-feeding you should not use [Product name] Nebuliser Solution unless your doctor tells you to. If you become pregnant whilst taking this medicine you should tell your doctor as soon as possible.

Driving and using machines

[Product name] Nebuliser Solution has no known effects on the ability to drive and use machines.

3. How to use [Product name] Nebuliser solution

Always use [Product name] Nebuliser Solution exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will probably tell you to use your nebuliser at regular times each day and you should always follow your doctor’s instructions.

The usual dose for adults (including the elderly) and adolescents over 12 years of age is the contents of one ampoule which should be taken three or four times a day.

[Product name] Nebuliser Solution is not to be used in children under 12 years of age.

General Instructions

Open each foil sachet one at a time and use all the ampoules inside before opening the next foil sachet. Always return any remaining ampoules to the foil sachet and place the sachet back in the carton after use. Since the ampoules do not contain a preservative, it is important to use them as soon as they are opened.

Instructions for use:

1. Prepare your nebuliser following the manufacturer's instructions and/or the dosing instructions given by your doctor
2. Take a strip of ampoules from the foil sachet. Remove one ampoule and put the rest back in the foil sachet and replace the foil sachet in the carton (see diagram 1). Never use an ampoule that has been opened already or if the solution is discoloured
3. Hold the ampoule upright and open it by twisting off the top (see diagram 2)
4. Unless otherwise instructed by your doctor, squeeze all of the liquid from the plastic ampoule into the nebuliser chamber
5. Throw away the empty plastic ampoule
6. Turn on the nebuliser and breathe in the "mist" calmly and deeply using the face mask or mouthpiece. If you are using a face mask make sure that it is fitted correctly. Protect your eyes from the mist produced as it can cause pain or discomfort if it gets into your eyes. This is especially important if you suffer from glaucoma.
7. The length of time it takes your nebuliser to turn your medicine into a mist will depend on the type of equipment you use. You will know when your treatment is complete because the fine mist will stop coming out of your mask or mouthpiece
8. You must wash your nebuliser, face mask and/or mouthpiece in warm soapy water and rinse well after each use.

[Product name] Nebuliser Solution should only be used in a nebuliser approved by your doctor and should not be mixed with other medicines in the same nebuliser.

Contact your doctor immediately if:

- **You are not getting relief from your current dose**
- **Your breathing is getting worse**
- **Your chest feels tight**

These are signs that your condition is not being controlled and you may need different or additional treatment.

If you use more [Product name] Nebuliser Solution than you should you may flush, feel shaky, muscle weakness, restless and/or dizzy, abnormal heart rhythm have chest pains and feel that your heart is beating faster than usual. Have high blood pressure or low blood pressure. Call your doctor immediately or go to the nearest hospital casualty department. If you feel shaky you should not drive. Take this leaflet or an ampoule of your medicine with you so that the hospital will know what you have taken.

If you forget to take your [Product name] Nebuliser Solution take the next dose when it is due or before you become wheezy. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, [Product name] Nebuliser Solution can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Rarely, inhaled drugs such as [Product name] Nebuliser Solution can cause acute wheezing and/or shortness of breath. If this occurs, stop using your medicine immediately and seek medical advice.

The following side effects have been reported:

Common side effects (may affect more than 1 in 10 people):

- Headaches
- Dry mouth
- Difficulty in speaking or hoarseness of the voice
- Palpitations (heart flutter)
- Feeling sick (nausea)
- Difficulty focussing your eyes
- Faster heartbeat
- Cough

Uncommon side effects (may affect up to 1 in 100 people):

- Dizziness
- Increases in blood pressure
- Being sick (vomiting)
- Difficulty passing urine
- Trembling or shaking, Nervousness
- Irregular heart beat

Rare side effects (may affect up to 1 in 1,000 people):

- Sweating
- Constipation
- Weakness and muscle pain/cramps
- Reduction in blood pressure and circulatory problems
- Restlessness
- Irritation of the mouth and throat
- Anxiety and depression, Memory problems
- Hyperactivity in children
- Eye problems including eye pain and glaucoma (increased pressure in the eye).

Not known (frequency cannot be estimated from the available data):

- Tooth decay
- 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.

If any of the solution or mist accidentally gets into your eyes, you may experience eye pain and/or inflammation, blurred vision and spots in front of your eyes. It is therefore important to be careful when using your medicine and to protect your eyes.

Sometimes this medicine can cause a lowering of potassium levels in the blood which can make you feel generally unwell. If you feel unwell, tell your doctor as they may wish to give you a blood test.

Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor/midwife if you develop these symptoms whilst receiving treatment with salbutamol, but do not stop using this medicine unless told to do so.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name] NEBULISER SOLUTION

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

Do not store above 25°C. Store the ampoules in the foil sachet in their original carton in order to protect them from light. Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton, foil sachet or ampoule after EXP:. The expiry date refers to the last date of that month.

Do not use this medicine if it appears to have deteriorated e.g. the pack is damaged or the solution is not clear.

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 [Product name] Nebuliser Solution contains:

- The active substances are Ipratropium bromide (0.5mg/2.5ml) and Salbutamol (as sulfate (2.5mg/2.5ml))
- The other ingredients are sodium chloride, hydrochloric acid and water for injections.

Each 2.5ml ampoule of [Product name] Nebuliser Solution contains 0.5mg of Ipratropium bromide and 2.5mg of Salbutamol (as sulfate).

What [Product name] Nebuliser Solution looks like and contents of the pack

[Product name] is a nebuliser solution.

Your medicine comes in the form of plastic ampoules containing 2.5ml of a clear colourless solution to be nebulised (made into a fine mist for inhalation). The ampoules are packed in strips inside a foil sachet which is then packed into a carton.

The cartons are available in pack sizes containing 10, 20, 40, 60, 80, 100 or 120 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer

<To be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names:

<[To be completed nationally]>

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