

PACKAGE LEAFLET: INFORMATION FOR THE USER

[Product Name] 250 micrograms/1ml Nebuliser Solution
[Product Name] 500 micrograms/2ml Nebuliser Solution
(Ipratropium Bromide)

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

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. 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.
4. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What [Product Name] Nebuliser Solution is and what it is used for
2. Before you take [Product Name] Nebuliser Solution
3. How to take [Product Name] Nebuliser Solution
4. Possible side effects
5. How to store [Product Name] Nebuliser Solution
6. Further information

1. WHAT [PRODUCT NAME] NEBULISER SOLUTION IS AND WHAT IT IS USED FOR

Ipratropium 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.

This medicine helps to make breathing easier in patients with asthma and other breathing difficulties such as chronic obstructive pulmonary disease.

[Product Name] Nebuliser Solution can be used at the same time as medicines called beta₂-agonist bronchodilators (‘relievers’), for example salbutamol.

2. BEFORE YOU TAKE [PRODUCT NAME] NEBULISER SOLUTION

Do not take [Product Name] Nebuliser Solution

- If you are allergic (hypersensitive) to ipratropium bromide or a related medicine called atropine
- If you are allergic to any of the other ingredients of [Product Name] Nebuliser Solution (these are listed in section 6, Further information).

Take special care with [Product Name] Nebuliser Solution

Talk to your doctor before taking this medicine if any of the following apply to you:

- if you suffer from cystic fibrosis
- if you have a condition which makes passing urine difficult
- if you suffer from raised pressure in the eyes (glaucoma), as you will need to make sure the mist does not get into your eyes
- if you are a man suffering from prostate problems

Taking other medicines

Tell your doctor if you are taking or have taken any of the following medicines as they may interact with [Product Name] Nebuliser Solution:

- medicines called xanthines such as theophylline
- other medicines containing bronchodilators (which also help you to breathe more easily), such as salbutamol or terbutaline

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

Pregnancy and breast-feeding

If you are pregnant, think you are pregnant or 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.

2. HOW TO TAKE [PRODUCT NAME] NEBULISER SOLUTION

Always use [Product Name] Nebuliser Solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor may tell you to use your nebuliser at regular times each day or only when you are wheezy or short of breath.

Adults, the elderly and children over 12 years

The usual dose is 250-500 micrograms (1-2ml of solution) three or four times a day. For acute attacks of breathlessness use 500 micrograms (2ml) of solution.

Children 6-12 years

The usual dose is 250 micrograms (1ml). The time between doses should be decided by the doctor.

Children up to 5 years

This medicine should only be used for acute attacks of breathlessness in children up to 5 years.

The usual dose is 125-250 micrograms (0.5-1 ml solution). The time between doses should be decided by the doctor but there should be at least 6 hours between doses.

In all cases, if breathlessness persists or becomes worse, tell your doctor.

General instructions:

[Product Name] Nebuliser Solution should be used with a suitable nebuliser. The “mist” produced is then inhaled through a face mask or mouthpiece. Your doctor will advise you on choosing an appropriate nebuliser and how it should be used.

Sometimes, this medicine is given using an intermittent positive pressure ventilator, in which case treatment will be started by your specialist.

Instructions for use:

1. Prepare your nebuliser following the manufacturer's instructions and/or the dosing instructions given by your doctor. Make sure it is clean.
2. Take a strip of ampoules from the foil sachet. Remove one or two ampoules (depending on your dose) (Diagram 1) and put the rest back in the foil sachet and replace the foil sachet in the carton. Never use an ampoule that has been opened already or if the solution is discoloured.

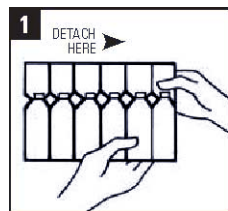


Diagram 1



Diagram 2

3. Hold the ampoule upright and open it by twisting off the top (Diagram 2)..
4. Unless otherwise instructed by your doctor, squeeze all the liquid from the ampoule into the nebuliser chamber.
5. Throw away the empty plastic ampoule
6. If your doctor has told you to dilute the solution, this should be carried out using ONLY sterile sodium chloride 0.9% solution. Use the amount which your doctor has told you to use.
7. 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. Be sure to protect your eyes from the mist produced as it can cause pain or discomfort if it gets into them. This is especially important if you suffer from glaucoma. If a lot of the mist gets into your eyes or you start suffering from eye pain or discomfort after using this medicine you should contact your doctor or pharmacist.
8. 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.
9. You must wash your nebuliser, face mask and/or mouthpiece in warm soapy water and rinse well after each use.

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 take more [Product Name] Nebuliser Solution than you should

You may feel that your heart is beating faster than usual or that your breathing becomes rapid. You may have a high fever, restlessness, confusion or hallucinations.

Call your doctor immediately or go to the nearest hospital casualty department .
Take this leaflet or an ampoule of your medicine with you so that the doctor will know what you have taken.

If you forget to take [Product Name] Nebuliser Solution

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 the one that you missed.

If you stop taking [Product Name] Nebuliser Solution this may make your condition worse. Do not stop taking your medicine unless your doctor tells you to do so.

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). This is known as 'angioedema'.

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 also been reported:

Common side effects (probably affecting up to 1 in 10 people)

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|------------------------------------|--|
| • Headache | • Nausea and/or vomiting (feeling or being sick) |
| • Cough | • Constipation |
| • Irritation of the nose and mouth | • Diarrhoea |
| • Dryness of the mouth | |

Uncommon side effects (probably affecting fewer than 1 in 100 people)

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| • Skin rashes (a rash of red spots or itchy 'nettle' rash) | • Blurred vision, difficulty focusing or other visual disturbances |
| • Rapid heartbeat | • Glaucoma (increased pressure in the eye) |

Rare side effects (probably affecting fewer than 1 in 1,000 people)

- Allergic reactions
- Swelling of the tongue, lips and face
- Increased pressure in the eye
- Irregular heartbeat
- Difficulty passing urine
- Pain in the eyes
- Widening of the pupils

If any of the solution or mist accidentally gets into your eyes you may experience red eyes, discomfort or pain in your eyes, blurred vision, or you may see halos or coloured images.

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

5. HOW TO STORE [PRODUCT NAME] NEBULISER SOLUTION

Keep out of the reach and sight of children.

Do not store your medicine above 25°C. Store in the original package in order to protect from light.

Do not use [Product Name] Nebuliser Solution after the expiry date which is stated on the ampoule label, foil sachet and carton.

The expiry date refers to the last day of that month.

Do not use [Product Name] Nebuliser Solution if you notice any cloudiness when the solution is poured into the nebuliser cup. Discard the solution and wash the nebuliser cup before selecting a fresh ampoule for use.

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 [Product Name] Nebuliser Solution contains

- The active ingredient is Ipratropium Bromide 250 micrograms/ml (0.025% w/v).
- The other ingredients are sodium chloride, water for injections and hydrochloric acid

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

Your medicine comes in the form of plastic ampoules containing a clear colourless solution to be nebulised (made into a fine mist for inhalation).

Two sizes of ampoules are available:

Ampoule containing 1ml of solution (250 micrograms of Ipratropium Bromide)

Ampoule containing 2ml of solution (500 micrograms of Ipratropium Bromide)

The ampoules are packed in strips of 10 inside a foil sachet which are then packed into a carton. Cartons are available in packs of 20 or 60 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

Laboratoire Unither, Espace Industriel Nord, 151 rue André Durouchez- CS 28028, 80084 AMIENS Cedex 2, France

This leaflet was last approved in: {mm/yyyy}