

Package Leaflet: Information for the User
VENTOLIN™ NEBULES™ 2.5mg/2.5ml
Nebuliser Solution

Salbutamol (as sulphate)

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, nurse or pharmacist.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

The name of your medicine

The name of your medicine is Ventolin Nebules 2.5mg/2.5ml Nebuliser Solution.

In this leaflet:

1. What Ventolin Nebules are and what they are used for
2. What you need to know before you take Ventolin Nebules
3. How to use Ventolin Nebules
4. Possible side effects
5. How to store Ventolin Nebules
6. Contents of the pack and other information

1. What Ventolin Nebules are and what they are used for

Ventolin Nebules 2.5mg/2.5ml and 5mg/2.5ml Nebuliser Solution (called 'Ventolin Nebules' in this leaflet) contain a medicine called salbutamol. This belongs to a group of medicines called bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Ventolin Nebules are used to treat breathing problems in people with asthma and other chest illnesses. They are usually given to people who suffer seriously from these conditions when other forms of treatment do not help enough. Ventolin Nebules are also given to treat severe attacks of asthma.

A Nebule is a small plastic container that contains a liquid. The liquid is put into a machine called a nebuliser. This machine makes a fine mist for you to breathe in through a face mask.

2. What you need to know before you take Ventolin Nebules

Do not use Ventolin Nebules if:

you are allergic (hypersensitive) to salbutamol sulphate or any of the other ingredients of Ventolin Nebules (listed in Section 6).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Ventolin Nebules if:

- you have high blood pressure
- you are diabetic
- you have an overactive thyroid gland
- you have a history of heart problems such as, severe heart failure, an irregular or fast heartbeat or angina
- you use another nebuliser solution e.g. ipratropium bromide, make sure the mist does not get in your eyes as there is a risk of glaucoma
- you suffer from acute severe asthma (your doctor may need to carry out blood tests to monitor the amount of potassium in your blood)

High doses of Ventolin Nebules can on rare occasions cause a condition known as lactic acidosis. You must look out for certain symptoms while you are taking Ventolin Nebules, to reduce the risk of any problems. See 'Possible side effects' in Section 4.

Use of this medicine should not cause difficulty in passing urine with the possible exception of male patients with enlarged prostate glands.

If you are using Ventolin Nebules at home and you notice the medicine is not working as well as usual, do not increase the dose and do not use the medicine more often, but tell your doctor as soon as possible.

Make sure the mist does not get in your eyes. This can be prevented by using a mouthpiece instead of a face mask or goggles.

Other medicines and Ventolin Nebules

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you go to hospital. In particular tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat e.g. propranolol
- other medicines for your asthma
- medicines used to treat high blood pressure eg guanethidine and methyldopa
- reserpine (used to treat high blood pressure or severe agitation)
- tricyclic antidepressants

Tell your doctor that you are taking Ventolin if you are going to have an operation as it may interact with some anaesthetics.

Ventolin Nebules with food and drink

You can use Ventolin Nebules at any time of day, with or without food.

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 or pharmacist for advice before taking this medicine.

Driving and using machines

Ventolin Nebules are not likely to affect you being able to drive or use any tools or machines.

You should not drive or use machinery while using the nebuliser.

3. How to use Ventolin Nebules

Always use Ventolin Nebules exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

- do not inject or swallow the liquid. Ventolin Nebules should only be inhaled using your nebuliser
- do not let the liquid, or the mist produced by the nebuliser get into your eyes. You can wear glasses or goggles to protect them
- your doctor, nurse or pharmacist should show you how to use your medicine
- each small plastic container (Nebule) contains some liquid
- the liquid is put into a nebuliser. This makes a fine mist for you to breathe in through a face mask or mouthpiece
- use your nebuliser in a well ventilated room as some of the mist will be released into the air and may be breathed in by others.

Dosing in adults and adolescents aged 12 years and over and children aged 4 to 11 years

The recommended dose is:

- The suitable starting dose is 2.5mg up to four times daily
- This may be increased to 5mg up to four times daily
- The maximum dose is 5mg four times daily

In adults, higher doses may be given for the treatment of severe airways obstruction but only under the direction and supervision of a doctor in hospital.

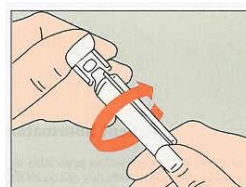
Other pharmaceutical forms may be more appropriate for children under 4 years.

Using your Nebules

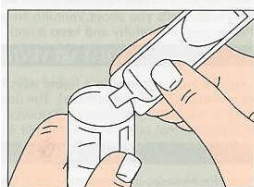
1. your Nebules are in a foil tray. Do not open the foil tray until you need to use them
2. open the foil tray by lifting the foil lid at the red arrow and peeling it back
3. hold the strip of Nebules in one hand, with your other hand hold the last Nebule in the row
4. twist the Nebule downwards and away from you



5. return the remaining Nebules to the foil tray, cover the tray with the foil lid and place the tray back in the box
6. hold the top of the Nebule you have just removed. Twist the body to open it



7. put the open end of the Nebule into the nebuliser bowl and squeeze slowly. Make sure that all the contents are emptied into the nebuliser



8. Assemble the nebuliser and use it as directed

Diluting your Nebules

- do not dilute the contents of a Nebule unless you are told to by your doctor
- if your doctor has told you to dilute the solution, empty the contents of the Nebule into the nebuliser bowl
- add the amount of sterile normal saline your doctor has told you to use
- put the top on the nebuliser bowl and shake gently to mix the contents.

If dilution is necessary then only sterile normal saline should be used.

After use

- use a fresh Nebule for each dose. Only open a new one when you are ready to use it. If there is any liquid left over, throw it away. Do not save it to use again
- throw away any solution remaining in the nebuliser bowl
- clean your nebuliser in the recommended way.

If you use more Ventolin Nebules than you should

If you use more than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky.
- These effects usually wear off in a few hours.

If you forget to use Ventolin Nebules

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Ventolin Nebules

Do not stop using Ventolin Nebules without talking to your doctor. If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4. Possible side effects

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately and tell your doctor as soon as possible.

Like all medicines, Ventolin Nebules can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic Reactions (affects less than 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin and see a doctor straight away.

Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

Talk to your doctor as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these affect less than 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible.

Do not stop using this medicine unless told to do so.

Lactic acidosis (affects less than 1 in 10,000 people)

An increase in the amount of lactic acid in the blood (lactic acidosis) is a very rare side effect of Ventolin Nebules. This most often affects people who have severe kidney disease. Symptoms of lactic acidosis include:

- rapid breathing, shortness of breath
- feeling cold
- stomach pain, nausea and vomiting.

Contact a doctor immediately if you get these symptoms.

Stop taking Ventolin Nebules.

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

Common (affects less than 1 in 10 people)

- feeling shaky
- headache.

Uncommon (affects less than 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

Rare (affects less than 1 in 1,000 people)

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral vasodilatation).

Very rare (affects less than 1 in 10,000 people)

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

Very rare side effects that may show up in blood tests

(affects less than 1 in 10,000 people)

- lactic acidosis

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

- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra Ventolin unless your doctor tells you to.

Reporting 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ventolin Nebules

Do not use Ventolin 2.5mg after the expiry date which is stated on carton after 'Exp'. The expiry date refers to the last day of that month.

Keep nebulisers in the outer carton.

Do not store above 30°C. Open one nebuliser at a time and once opened, use immediately.

Use Nebules within three months of opening the outer foil packaging. Do not use if the solution appears discoloured.

KEEP OUT OF SIGHT AND OF REACH OF CHILDREN

If you are told to stop taking this medicine return any unused Ventolin Nebules to your pharmacist to be destroyed.

6. Contents of the pack and other information

What Ventolin Nebules contains

The active substance is salbutamol (as sulphate).

Each Nebule contains 2.5mg Salbutamol (as sulphate).

Each ml of solution contains 1mg Salbutamol (as sulphate).

The other ingredients are sodium chloride, dilute sulphuric acid, water for Injections.

What Ventolin Nebules looks like and contents of the pack

Each foil tray contains 5 Ventolin Nebules linked together in a strip.

Ventolin Nebules are available in packs of 20 Nebules.

WHO MAKES YOUR MEDICINE?

Ventolin Nebules 2.5mg are made by Glaxo Wellcome GmbH & Co., Bad Oldesloe, Germany.

Procured from within the EU and repackaged by PPA holder:

B & S Healthcare, Unit 4 Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

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This leaflet does not tell you everything about your medicine. If you have any questions or are not sure about anything, then ask your doctor or pharmacist. Alternatively, the Asthma Society of Ireland would be happy to answer some of these issues for you. Further information is available by writing to them at 26 Mountjoy Square, Dublin 1 or by telephone 01 8788511

You may need to read this leaflet again. Do not throw it away until you have finished your Nebules.

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