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Package leaflet: Information for the user

Ventolin Injection 500 micrograms/ml salbutamol sulfate

Read all of this leaflet carefully before you start taking 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 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Ventolin Injection is and what it is used for
- 2 What you need to know before you use Ventolin Injection
- 3 How to use Ventolin Injection
- 4 Possible side effects
- 5 How to store Ventolin Injection
- 6 Contents of the pack and other information

1 What Ventolin Injection is and what it is used for

Ventolin Injection contains 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 Injection is used to treat severe breathing problems in people with asthma and similar conditions.

2 What you need to know before you use Ventolin Injection

Do not use Ventolin Injection:

- if you are allergic to salbutamol sulfate or any of the other ingredients of this medicine (listed in Section 6)
 - if you unexpectedly go into early labour (premature labour) or threatened abortion
- Do not take if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Ventolin Injection.

Warnings and precautions

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

- you have high blood pressure
- you are diabetic
- you have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition
- you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma

Other medicines and Ventolin Injection

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular tell your doctor or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat
- other medicines for your asthma

Ventolin Injection should not be administered in the same syringe as any other medication.

Using Ventolin Injection with food and drink

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

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Ventolin Injection is not likely to affect you being able to drive or use any tools or machines.

Information about sodium content

This medicinal product contains less than 1 mmol sodium (23 mg) per 5ml ampoule, i.e. essentially 'sodium-free'.

3 How to use Ventolin Injection

How your Injection is given

Ventolin Injection is usually given to you by a doctor or nurse. It can be given under the skin (subcutaneously) or directly into a vein or muscle (intravenous or intramuscular route). You will never be expected to give yourself this medicine. It will always be given to you by a person who is qualified to do so.

The ampoules are equipped with the OPC (One Point Cut) opening system and must be opened using the following instructions:

- hold with one hand the bottom part of the ampoule
- put the other hand on the top of the ampoule positioning the thumb above the coloured point and press

Subcutaneous or Intramuscular route

- The usual dose is 8 micrograms per kilogram body weight every four hours.

Slow Intravenous injection

- The usual dose is 4 micrograms per kilogram body weight.
- This will be injected slowly and may be repeated if necessary.
- Ventolin Injection may be diluted with 10 ml Water for Injections.
- 5 ml of the diluted preparation (250 micrograms per 5 ml) may be administered by slow intravenous injection.

Ventolin Injection is not suitable for treating children under 12 years of age.

If you receive more Ventolin Injection than you should

Ventolin Injection will always be given under carefully controlled conditions. However, if you think that you have been given more than you should tell your doctor or nurse as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky
- hyperactivity
- acid build up in your body which may cause your breathing to become faster

These effects usually wear off in a few hours.

If you stop taking Ventolin Injection

Do not stop taking Ventolin Injection without talking to your doctor.

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

4 Possible side effects

Like all medicines, Ventolin Injection 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 Injection 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.**

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

Very common (may affect more than 1 in 10 people)

- feeling shaky

Common (may affect up to 1 in 10 people)

- headache
- muscle cramps

Uncommon (may affect up to 1 in 100 people)

- patients receiving Ventolin Injection for the treatment of premature labour: cough, wheezing, chest pain or shortness of breath, which may be signs of pulmonary oedema (fluid in the lungs). Tell your doctor immediately

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

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

Very rare (may affect up to 1 in 10,000 people)

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

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

- stinging or pain when the injection is given directly into the muscle
- feeling sick and being sick (nausea and vomiting)
- 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
- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath, cold feet and hands, irregular heartbeat or thirst

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 Injection unless your doctor tells you to.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5 How to store Ventolin Injection

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Keep the ampoules in the outer carton to protect from light.
- Use the medicine within 24 hours of mixing with infusion fluids.
- Do not use this medicine after the expiry date, which is stated on the ampoule label and carton after 'EXP'. The expiry date refers to the last day of that month.
- If you are told to stop taking this medicine return any unused Ventolin Injection to your pharmacist to be destroyed.

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 to protect the environment.

6 Contents of the pack and other information

What Ventolin Injection contains

- The active substance is salbutamol sulfate.
- The other ingredients are water, salt (sodium chloride), sodium hydroxide, sulfuric acid, nitrogen.

What Ventolin Injection looks like and contents of the pack

Ventolin Injection comes in a 1 ml glass ampoule in plastic trays of five.

5 ml contains 2.5 mg of salbutamol (as salbutamol sulfate) in sterile normal saline adjusted to pH 3.5.

Each carton contains 5 ampoules.

Marketing Authorisation Holder

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Ventolin Injection**
Reference number 10949/0084

This is a service provided by the Royal National Institute of Blind People.

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