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Package leaflet: Information for the user

## **Ventolin Solution for Intravenous Infusion 1 mg/ml salbutamol sulfate**

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

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

### **1 What Ventolin Infusion is and what it is used for**

Ventolin Solution for Intravenous Infusion (called 'Ventolin Infusion' in this leaflet) contains a medicine called salbutamol. This belongs to a group of medicines called 'beta-agonists'. It acts on special receptor sites in the lungs and in the uterus (in women) to:

- help the airways in your lungs to stay open. This makes it easier for air to get in and out. It helps to relieve chest tightness, wheezing and cough
- relax the muscles in the walls of the uterus. This may stop the contractions associated with labour.

Ventolin Infusion is used:

- to treat severe breathing problems in people with asthma and similar conditions
- in women who have unexpectedly gone into early labour (premature labour) between the 22<sup>nd</sup> and 37<sup>th</sup> week of gestation, to provide a short delay in the early delivery of the baby. You will receive Ventolin Infusion for a maximum of 48 hours. This will give your doctor or midwife time to take extra measures that will improve the health of your baby.

### **2 What you need to know before you use Ventolin Infusion**

**Do not use Ventolin Infusion if:**

- you are allergic to salbutamol sulfate or any of the other ingredients of this medicine (listed in section 6)
- you are less than 22 weeks pregnant
- you suffer from or have a known risk of developing ischaemic heart disease (disease characterized by reduced blood supply to your heart muscle, causing symptoms such as chest pain (angina))
- you have ever experienced miscarriage in the first two trimesters of your pregnancy
- you are pregnant and you or your baby have certain conditions when prolongation of your pregnancy would be dangerous (such as severe high blood pressure, infection of the womb, bleeding, placenta is covering the birth canal or is detaching, or your baby has died inside the womb)

- you suffer from heart disease with palpitations (for example heart valve disorder) or long-standing lung disease (for example chronic bronchitis, emphysema) causing an increase of blood pressure to your lungs (pulmonary hypertension).

### **Warnings and precautions**

Talk to your doctor or nurse before having your injection if:

- you have had problems with your pregnancy
- during pregnancy, your waters have broken
- you have too much fluid in the lungs causing breathlessness (pulmonary oedema)
- you have high blood pressure
- you are diabetic. If so, you may need some additional blood sugar tests when you are given Ventolin Infusion
- you have an overactive thyroid gland
- you have a history of heart disease characterised by breathlessness, palpitations or angina (see **Do not use Ventolin Infusion if**).

If you are given Ventolin Infusion for a short delay in the delivery of a baby, your doctor will monitor your heart and your unborn baby. Your doctor may also take blood tests to monitor for changes in your blood (see section 3).

### **Other medicines and Ventolin Infusion**

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. Ventolin Infusion can have an effect on the way some medicines work, and some medicines can affect how Ventolin Infusion works.

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

- medicines for an irregular or fast heartbeat (such as digoxin)
- other beta-blocker medicines (such as atenolol or propranolol), including eye drops (such as timolol)
- xanthine medicines (such as theophylline or aminophylline)
- steroid medicines (such as prednisolone)
- water tablets, also known as diuretics (such as frusemide)
- medicines for diabetes to reduce your blood sugar (such as insulin, metformin or glibenclamide)
- other medicines for your asthma.

Ventolin Infusion should not be administered in the same syringe or infusion as any other medication.

If you are scheduled for surgery with general anaesthetics your doctor will stop the administration of Ventolin Infusion 6 hours before surgery whenever possible to protect you from adverse effects (e.g. irregular heart beat or bleeding of your womb).

### **Using Ventolin Infusion with food and drink**

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

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or 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 Infusion is not likely to affect you being able to drive or use any tools or machines.

### **Information on 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 Infusion**

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. Where Ventolin infusion is used to temporarily delay premature labour, it will always be given to you by a person who is qualified to do so after careful consideration of the balance of benefits of Ventolin Infusion to your baby and the potential untoward effects the treatment may have on you.

**The Ventolin Infusion will be diluted before it is given to you.** Your doctor or nurse will find information about how to dilute the medicine in the Summary of Product Characteristics (SPC).

#### **To treat severe breathing problems**

- The usual dose is 3 to 20 micrograms of salbutamol per minute for as long as required.
- Higher doses may be used in patients with 'respiratory failure'.

#### **To temporarily delay premature labour**

- The usual dose is 10 to 45 micrograms of salbutamol per minute until contractions stop.
- If your labour continues despite this treatment then the infusion should be stopped.

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

You will be given Ventolin Infusion by a doctor where facilities are available to continually monitor your health and that of your baby throughout administration.

The following measures will be taken where necessary:

- Blood pressure and heart rate. Your doctor will consider the lowering of your dose or discontinuing Ventolin Infusion if your heart rate exceeds 120 beats per minute.
- Electrocardiography (ECG, electric activity of your heart). **Tell your doctor immediately if you experience chest pain during treatment.** If there are changes in ECG recording and you have chest pain your doctor will stop the administration of Ventolin Infusion.
- Balance of water and salts in your body. **Tell your doctor immediately if you experience coughing or shortness of breath during treatment.** If any signs indicate that there is a build-up of fluid in your lungs (also known as pulmonary oedema) (e.g. coughing or shortness of breath), your doctor may stop the administration of Ventolin Infusion.
- Blood sugar level and the occurrence of low body pH with a build-up of lactate in your blood (also known as lactic acidosis).
- Blood potassium levels (low potassium levels may be associated with a risk of irregular heart beat).

#### **If you receive more Ventolin Infusion than you should**

Ventolin Infusion 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 Infusion**

Do not stop taking Ventolin Infusion 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, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

### **Allergic reactions** (may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin Infusion 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.

### **Important side effects to look out for when treated for premature labour:**

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

- chest pain (due to heart problems such as angina). **If this happens to you, tell your doctor or nurse straight away.**

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
- \*<sup>1</sup>fast heart beats.

#### **Common** (may affect up to 1 in 10 people)

- headache
- muscle cramps
- \*<sup>1</sup>pounding heart beat (palpitations)
- \*low blood pressure which may cause light-headedness or dizziness
- \*low levels of potassium in your blood which may cause muscle weakness, thirst, or “pins and needles”.

#### **Uncommon** (may affect up to 1 in 100 people)

- \*<sup>1</sup>fluid accumulation in the lungs (pulmonary oedema) which may cause difficulty breathing.

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

- \*<sup>1</sup>unusual or irregular heartbeats
- \*high levels of sugar (glucose) and/or lactic acid in your blood
- \*<sup>1</sup>flushing (reddening) of the face
- low levels of potassium in your blood which may cause muscle weakness, thirst, or “pins and needles”.

#### **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:**

- in the treatment of premature labour feeling sick and being sick (nausea and vomiting)

- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath, cold feet and hands, irregular heartbeat or thirst.

\*The following side effects have also been observed with all beta-agonists like Ventolin Infusion when used to delay premature labour.

<sup>1</sup> The following side effects have also been observed when Ventolin Infusion is used to treat severe breathing problems as well as observed when used to delay premature labour.

### **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 Infusion 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](http://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 Infusion**

- 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 Ventolin Infusion 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 Infusion 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 protect the environment.

## **6 Contents of the pack and other information**

### **What Ventolin Infusion contains**

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

### **What Ventolin Infusion looks like and contents of the pack**

Ventolin Infusion comes in a 5 ml glass ampoule.

Each 5 ml ampoule contains 5 mg of salbutamol sulfate in sterile normal saline adjusted to pH 3.5.

Each carton contains 10 ampoules.

### **Marketing Authorisation Holder**

Glaxo Wellcome UK Limited  
GSK Medicines Research Centre  
Gunnels Wood Road  
Stevenage  
Hertfordshire  
SG1 2NY

UK

**Manufacturer**

GlaxoSmithKline Manufacturing S.p.A.  
San Polo di Torrile  
Parma  
Italy

**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 Infusion**  
Reference number        10949/0087

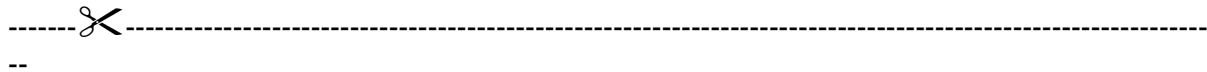
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**The following information is intended for Medical or Healthcare Professionals only**

**Ventolin Solution for Intravenous Infusion 1 mg/ml  
salbutamol sulfate**

**To treat severe bronchospasm**

Dilute 5 ml of Ventolin Solution for Intravenous Infusion to 500 ml with Sodium Chloride and Dextrose Injection, Water for Injections, Sodium Chloride Injection or Dextrose Injection.

**To treat premature labour**

- a) using a syringe pump. Dilute 10 ml of Ventolin Solution for Intravenous Infusion with 40 ml of 5% dextrose solution and administer at a rate of 0.05 to 0.225 ml/minute
- b) other infusion methods. Dilute 10 ml of Ventolin Solution for Intravenous Infusion with 490 ml of 5% dextrose solution and administer at a rate of 0.5 to 2.25 ml/minute.

Please refer to the Summary of Product Characteristics for more details.

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.

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