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Package Leaflet: Information for the User

Ventolin 1 mg/ml Concentrate for Solution for Intravenous Infusion salbutamol (as 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 any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

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 1mg/ml Concentrate for 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 in adults and adolescents (children aged 12 years and over):

- to treat severe breathing problems in people with asthma and similar conditions

Ventolin Infusion is also used in women who have unexpectedly gone into early labour (premature labour) between the 22nd and 37th 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 have Ventolin Infusion if:

- you are allergic (hypersensitive) to salbutamol sulfate or any of the other ingredients of Ventolin Infusion (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 have pre-eclampsia (high blood pressure, fluid retention and/or protein in the urine)
- you suffer from heart disease with palpitations (for example heart valve disorder) or longstanding lung disease (for example chronic bronchitis, emphysema) causing an increase of blood pressure to your lungs (pulmonary hypertension)

If you are not sure if the above applies to you, talk to your doctor, nurse or pharmacist before taking Ventolin Infusion.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before having Ventolin Infusion 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, palpitation or angina (**see ‘Do not have Ventolin Infusion if’**)
- you suffer from acute severe asthma (your doctor may need to carry out blood tests to monitor the amount of potassium in your blood).

If you have existing heart problems your doctor will assess you **before** you are treated with this medicine for premature labour.

Your doctor will monitor your heart and your unborn baby. Your doctor may also take extra blood tests to monitor for changes in your blood (see section 3).

If your asthma or breathing gets worse tell your doctor straight away. Your chest condition may be getting worse and you could become seriously ill

Children

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

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)
- other medicines for your asthma.
- steroid medicines (such as prednisolone)
- medicines used to treat high blood pressure e.g. guanethidine and methyldopa
- reserpine (used to treat high blood pressure or severe agitation)
- tricyclic antidepressants
- water tablets, also known as diuretics (such as furosemide)
- medicines for diabetes to reduce your blood sugar (such as insulin, metformin or glibenclamide)

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).

Use of this medicine will lessen the effect of medicines used to induce labour.

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

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 or pharmacist for advice before taking this medicine.

Driving and using machines

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

Ventolin Infusion contains sodium

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

How your Ventolin Infusion is given

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 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.

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 beats faster than usual
- you feel shaky
- hyperactivity
- acid builds 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 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 (affects less than 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.

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 more 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.

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

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

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

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.
- 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 effect can also happen but the frequency of this is 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

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.

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

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

- Fast heart beats

Common (may affect up to 1 in 10 people)

- 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)

- Fluid accumulation in the lungs (pulmonary oedema) which may cause difficulty breathing

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

- Unusual or irregular heartbeats
- High levels of sugar (glucose) and/or lactic acid in your blood
- Flushing (reddening) of the face

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

- feeling sick and being sick (nausea and vomiting)

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

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 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 HPRa Pharmacovigilance, Website: www.hpra.ie. 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.
- 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 to protect the environment.

6 Contents of the pack and other information

What Ventolin Infusion contains

- The active substance is salbutamol (as sulfate).
- The other ingredients are water for injections, salt (sodium chloride), dilute sulphuric acid and sodium hydroxide (for pH adjustment).

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 (as sulfate) in sterile normal saline adjusted to pH 3.5.

Each carton contains 10 ampoules.

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Marketing Authorisation Holder

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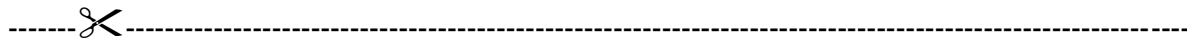
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THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

(Please refer to the Summary of Product Characteristics for further information)

Pharmaceutical form

Ventolin 1mg/ml Concentrate for Solution for Intravenous Infusion

Posology and method of administration

Salbutamol has a duration of action of 4 to 6 hours in most patients.

Ventolin parenteral preparations are to be used under the direction of a physician.

Increasing use of beta-2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

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

The contents of the ampoules of Ventolin Concentrate Solution for Intravenous Infusion must not be injected undiluted. The concentration should be reduced by 50% before administration.

Adults and Adolescents (children aged 12 years and over):

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In bronchospasm and status asthmaticus:

Intravenous slow injection:-

Infusion rates of 3 to 20 micrograms per minute are generally adequate but in patients with respiratory failure, higher dosage has been used with success. A starting dose of 5 micrograms per minute is recommended with appropriate adjustment in dosage according to patient response.

A suitable solution for infusion may be prepared by diluting 5ml of Ventolin Concentrate Solution for Intravenous Infusion in 500ml of an infusion solution such as sodium chloride and dextrose injection BP to provide a salbutamol dose of 10 mcg/ml of solution.

In the short term management of uncomplicated premature labour.

Treatment with Ventolin Infusion should only be initiated by obstetricians/physicians experienced in the use of tocolytic agents. It should be carried out in facilities adequately equipped to perform continuous monitoring of maternal and foetus health status.

Duration of treatment should not exceed 48 hours as data show that the main effect of tocolytic therapy is a delay in delivery of up to 48 hours; no statistically significant effect on perinatal mortality or morbidity has been observed in randomised, controlled trials. This short term delay may be used to administer glucocorticoids or to implement other measures known to improve perinatal health.

Ventolin Infusion should be administered as early as possible after the diagnosis of premature labour, and after evaluation of the patient to eliminate any contra-indications to the use of salbutamol (see section 4.3 of the Summary of Product Characteristics). This should include an adequate assessment of the patient's cardiovascular status with supervision of cardiorespiratory function and ECG monitoring throughout treatment (see section 4.4 of the Summary of Product Characteristics).

Intravenous Infusion:-

Infusion rates of 10-45 micrograms per minute are generally adequate. A starting rate of 10 micrograms per minute is recommended, increasing the rate until there is evidence of patient response.

Special cautions for infusion: The dose must be individually titrated. The infusion rate may be increased slowly until contractions cease. Careful attention should be given to cardio-respiratory function, including increases in pulse rate and changes in blood pressure, electrolytes, glucose and lactate levels and fluid balance monitoring. These parameters should be carefully monitored during treatment. A maximum maternal heart rate of 120 beats per min should not be exceeded.

Careful control of the level of hydration is essential to avoid the risk of maternal pulmonary oedema (see section 4.4 of the Summary of Product Characteristics). The volume of fluid in which the drug is administered should thus be kept to a minimum. A controlled infusion device should be used, preferably a syringe pump.

Treatment should be discontinued should signs of pulmonary oedema or myocardial ischaemia develop. (see section 4.4 and section 4.8 of the Summary of Product Characteristics).

Once uterine contractions have ceased the infusion rate should be maintained at the same level for one hour and then reduced by 50% decrements at 6-hourly intervals.

Paediatric Population:

The safety and efficacy of Ventolin Concentrate for Solution for Intravenous Infusion in children under the age of 12 years has not been established. From the available data no recommendation on posology can be made.

Overdose

The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events.

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.

Treatment

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

Shelf life and special precautions for storage

Unopened: 48 months.

Once opened and diluted: Use immediately. Discard any unused contents.

Chemical and physical in-use stability has been demonstrated for 24 hours at 20-25°C.

From a microbiological point of view, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Do not store above 30°C.

Keep the ampoules in the outer carton to protect from light.

Instructions for use and handling

To open the ampoule:

- Flick down any liquid in the ampoule neck.
- Hold ampoule upright.
- Break off the top tag in one quick turn.
- Attach syringe direct to ampoule or insert syringe.
- Withdraw contents using firm consistent pressure.

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Dilute before use.
For single use only.
Discard any unused contents.

The following infusion fluids are compatible with Ventolin 1mg/ml Concentrate for Solution for Intravenous Infusion:

- 5% w/v Dextrose Injection BP
- 0.9% w/v Sodium Chloride Injection BP
- 0.18% Sodium Chloride and
- 4% w/v Dextrose Intravenous Infusion BP

Chemical and physical in-use stability has been demonstrated for 24 hours at 20-25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.