Reason for update: Type IB – Shelf life extension from 36 months to 48 months
HPRA Approval date:
Text Date: 06/02/2024
Text Issue and Draft No.: Issue 5 Draft 1

GSK logo

Package Leaflet: Information for the User

Ventolin 500 micrograms/ml Solution for Injection

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 you get 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 Injection is and what it is used for

Ventolin 500 micrograms/ml Solution for Injection (called 'Ventolin Injection' 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 Injection 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 Injection 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 Injection 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 Injection

Do not have Ventolin Injection if:

- you are allergic (hypersensitive) to salbutamol sulfate or any of the other ingredients of Ventolin Injection (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)

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

Warnings and precautions
Talk to your doctor, nurse or pharmacist before having Ventolin 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 Injection.
- you have an overactive thyroid gland
- you have a history of heart disease characterised by breathlessness, palpitations or angina **(see 'Do not have Ventolin Injection 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 Injection is not suitable for treating children under the age of 12 years.

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

In particular tell your doctor 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 Injection 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 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 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 Injection 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 Injection

How your Ventolin Injection 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 Injection to your baby and the potential untoward effects the treatment may have on you.

To treat severe breathing problems
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.

To temporarily delay premature labour
- Ventolin Injection may be given as a single injection by the intravenous route.

- The usual dose is 100 micrograms to 250 micrograms.

You will be given Ventolin Injection 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 Injection 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 Injection.
- 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 Injection.
- 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 heartbeat)

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 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 Injection
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 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 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)
- a 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.
- stinging or pain when the injection is given directly into the muscle

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 Injection when used to delay premature labour.

Very common (may affect up to 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 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.
- Do not use Ventolin Injection 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 pack and other information

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

What Ventolin Injection looks like and contents of the pack
Ventolin Injection comes in a 1 ml glass ampoule in plastic trays of five.
Each ml contains 500 micrograms salbutamol as salbutamol sulfate.
Each carton contains 5 ampoules.

Marketing Authorisation Holder
GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24, Ireland

Manufacturer
GlaxoSmithKline Manufacturing S.p.A.
Strada Provinciale Asolana 90,
43056 San Polo di Torrile
Parma
Italy

This leaflet was last revised in February 2024.

-------✂----------

GSK Logo

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 500 micrograms/ml Solution for Injection

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 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 be administered in the same syringe or infusion as any other medication.

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

In bronchospasm and status asthmaticus:

Subcutaneous Route: 500 micrograms (8 mcg/kg bodyweight) and repeated every four hours as required.

Intramuscular Route: 500 micrograms (8 mcg/kg bodyweight) and repeated every four hours as required.

Intravenous Route: 250 micrograms (4 mcg/kg bodyweight) injected slowly. If necessary, the dose may be repeated. A solution of 250 micrograms in 5 ml is ordinarily used.

In the short term management of uncomplicated premature labour
Treatment with Ventolin Injection 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 Injection 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).

Ventolin Injection may be administered as a single injection by the intravenous route. The usual recommended dose is 100 to 250 micrograms of salbutamol.

Special cautions for infusion: The dose must be individually titrated. 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)

Paediatric Population:
The safety and efficacy of Ventolin Injection 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: 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.

The following infusion fluids are compatible with Ventolin 500 mg/ml Solution for Injection:
• 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 20-25ºC. 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 2-8ºC, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

For single use only. Discard any unused contents.