

Ventolin[®] Obstetric Injection

Salbutamol sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ventolin Obstetric Injection. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ventolin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is Ventolin Obstetric Injection is used for?

Ventolin Obstetric injection is used to stop contractions of premature labour between weeks 24 and 37 of pregnancy.

Your medicine relaxes the muscles in the uterus and stops contractions due to labour during this stage of pregnancy.

Ventolin Obstetric injection may not be as effective if your 'waters break' or the neck of the uterus has widened.

Ventolin Obstetric Injection is not addictive.

Before you are given Ventolin Obstetric Injection

When you must not have it:

- If you have ever had an allergic reaction to salbutamol sulphate or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")

Some of the symptoms of an allergic reaction may include:

- Shortness of breath.
- Wheezing or difficulty in breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin
- **you are less than 24 weeks pregnant**
- **if you have any problem where it would not be safe to prolong the pregnancy**
- **you have asthma**

- **if you have a thyroid problem associated with pregnancy**
- **you have been have or are having treatment for high blood pressure, including high blood pressure associated with pregnancy**
- **you have pre-existing heart disease or rapid heart beats**
- **if you have any problem with the bowels**
- **you have a kidney problem**
- **you have diabetes**
- **you have eye problems due to the condition known as glaucoma**
- **you have, or have had, bleeding from the vagina**
- **your 'waters break' - you have had a 'show' or fluid leaking from the vagina**
- **you are aware of any problem with your unborn child**
- **you know you are having more than one baby**
- **After the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines**
- **you are taking any other medicines, including medicines you buy without a prescription**
- **you have had to stop taking this or any other asthma medicine for any reason**
- **you have a thyroid problem**
- **you have a heart problem**
- **you are aware of any problem that may cause low blood potassium**
- **you have a liver problem**
- **you suffer from anxiety or panic attacks**
- **you have had to stop taking this or any other medicine for treating labour in pregnancy**
- **you have any other medical problem due to your pregnancy**

How do I use Ventolin Obstetric Injection?

How to take it

Ventolin Obstetric injection must only be given by a doctor or physician who are experienced in giving tocolytic agents (which are used to treat premature labour).

The liquid in Ventolin Obstetric injection is diluted before use and is given by infusion (sometimes called a 'drip') into a vein. Often a special pump is used to deliver the medicine slowly into the vein.

Do not try to use Ventolin Obstetric Injection on your own.

How long you will be given it

Ventolin Obstetric Injection should not be given for more than 48 hours at a time.

What do I do if I have too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (In call 131126. In new Zealand call 0800 POISON or 0800 764 766) for advice, if you think you or anyone else may have been given too much Ventolin Obstetric Injection, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

Symptoms of an overdose may include:

- your heart beating significantly faster than normal
- significant muscle tremors

- an increased rate of breathing due to increased acid in the blood

Some side effects, for example changes in blood sugar (glucose) level or changes in blood potassium level can only be found when your doctor does tests from time to time to check your progress.

While you are given Ventolin Obstetric Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Ventolin Obstetric Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during the surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if you become pregnant or are breast-feeding.

Your doctor will tell you which medicine you should take. It is important that asthma is managed well during pregnancy and you should not stop your medicine without asking your doctor.

Things you must not do

Do not use Ventolin Obstetric Injection to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

What are the side effects?

Like other medicines, Ventolin Obstetric Injection can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention. Your doctor, pharmacist or nurse will be able to answer any questions you may have.

If you have any of the following side-effects, tell your doctor or nurse:

The most commonly reported side-effects are:

- 'shakiness' of the muscles
- you are aware of your heartbeat
- your heart beats faster than normal
- your heartbeat does not feel regular

- 'warm' feeling
- anxious or tense feeling
- headache
- increased blood flow to the extremities (peripheral vasodilation)
- high blood pressure

Rare side effects are:

- nausea or sick feeling
- Muscle cramps
- Shortness of breath
- Low blood pressure
- Hyperactivity

The following side effects may also happen but the frequency of these is unknown:

- Sweating / chills
- Constipation or diarrhoea or other bowel trouble
- Jaundice (yellow skin or eyes)
- Difficulty sleeping
- Drowsiness and weakness

Tell your doctor or nurse immediately if you notice any of the following:

- **skin rash**
- **angioedema (sudden swelling under the skin)**
- **faint or dizzy feeling**
- **wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**

In a few cases, the medicine in Ventolin Obstetric injection may result in fluid collecting in the lungs. To prevent this, your doctor or nurse will carefully measure how much urine you pass and how much liquid you drink, and check your heart and lungs. If you feel breathless or start coughing when your medicine is given or just after, tell your doctor or nurse immediately.

Occasionally, the medicine in Ventolin Obstetric Injection may result in a loss of or reduction in blood flow (ischaemia) to the heart. Your doctor may do tests on your heart to check this.

Very rarely, in people receiving high dose treatment with this medicine and in patients with an acute exacerbation of asthma, a serious condition called acidosis, which affects the blood may occur because of build up of lactic acid. Your doctor may do tests to check this.

In a few people, the medicine in Ventolin Obstetric Injection may affect their blood sugar or potassium levels. Your doctor may do tests to check this.

If you have other problems after receiving Ventolin Obstetric Injection, tell your doctor or nurse.

Your unborn child may have an increased heartbeat. Very rarely, the unborn child may have low blood sugar or lack of bowel movement.

If you receive too high a dose of Ventolin Obstetric Injection, your heart will beat faster than normal and you will feel 'shaky'.

This is not a complete list of all possible side effects. If you want more information, ask your doctor or nurse.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Ventolin Obstetric Injection?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

A locked cupboard at least one-and-a-half metres above ground is a good place to store medicines

Keep Ventolin Obstetric Injection must be kept away from heat (store below 30°C) and protected from light.

Do not leave in a car, on a window sill or in a bathroom.

Heat and dampness can destroy some medicines.

Product description

What Ventolin Obstetric Injection looks like

Ventolin Obstetric Injection is stored in clear glass ampoules. Each ampoule of Ventolin Obstetric Injection contains 5 mL of liquid and provides 5 mg of salbutamol sulphate.

The liquid is either colourless or pale straw coloured.

Ingredients

Ventolin Obstetric Injection contains the active ingredient Salbutamol sulfate.

Ventolin Obstetric Injection also contains the inactive ingredients sodium chloride, water and dilute sulphuric acid for pH adjustment.

There are 5 ampoules in a box.

Sponsor

Ventolin Obstetric Injection is supplied in Australia by:

Allen & Hanburys

A division of GlaxoSmithKline Australia Pty Ltd

Level 4

436 Johnston Street

Abbotsford Victoria 3067

Australia

This leaflet was prepared on 2 July 2014

The information provided applies only to: Ventolin[®] Obstetric Injection.

Ventolin is a registered trade mark of the GlaxoSmithKline group of companies.

Ventolin Obstetric Injection: AUST R 12528

©2014 GlaxoSmithKline

Version 2.0