

# VENTOLIN OBSTETRIC INJECTION

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## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### **1. Why am I being given VENTOLIN OBSTETRIC INJECTION?**

VENTOLIN OBSTETRIC INJECTION contains the active ingredient salbutamol sulfate. VENTOLIN OBSTETRIC INJECTION is used to stop contractions of premature labour between weeks 24 and 33 of pregnancy.

For more information, see Section [1. Why am I being given VENTOLIN OBSTETRIC INJECTION?](#) in the full CMI.

### **2. What should I know before I am given VENTOLIN OBSTETRIC INJECTION?**

Do not use if you have ever had an allergic reaction to salbutamol sulfate or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or have any other medical problem due to your pregnancy.**

For more information, see Section [2. What should I know before I am given VENTOLIN OBSTETRIC INJECTION?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with VENTOLIN OBSTETRIC INJECTION and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How is VENTOLIN OBSTETRIC INJECTION given?**

- VENTOLIN OBSTETRIC INJECTION must only be given by a doctor or physician who is experienced in giving tocolytic agents (which are used to treat premature labour).

More instructions can be found in Section [4. How is VENTOLIN OBSTETRIC INJECTION given?](#) in the full CMI.

## 5. What should I know when being given VENTOLIN OBSTETRIC INJECTION?

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>• Remind any doctor you visit that you are using VENTOLIN OBSTETRIC INJECTION.</li> <li>• Tell your doctor if you are going to have surgery and tell your surgeon or anaesthetist that you are using this medicine.</li> <li>• Discuss your pregnancy and breastfeeding with your doctor.</li> <li>• Discuss your asthma management with your doctor. It is important that asthma is managed well during pregnancy, and you should not stop your asthma medication without asking your doctor.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• VENTOLIN OBSTETRIC INJECTION will be given to you in a hospital or clinic and the healthcare professionals will be</li> </ul>

	responsible for its storage. It should be stored below 30°C away from moisture, heat, or sunlight.
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For more information, see Section [5. What should I know when being given VENTOLIN OBSTETRIC INJECTION?](#) in the full CMI.

## **6. Are there any side effects?**

Less serious side effects which have been reported include 'shakiness' of muscles, awareness of heartbeat, increased heartbeat, irregular heartbeat, anxious or tense feeling, headache, increased blood flow to extremities, and high blood pressure. Serious side effects include skin rash, angioedema (sudden swelling under the skin), faint or dizzy feeling, 'warm' feeling, allergic reaction, fluid collecting in lungs, reduction of blood flow to the heart, acidosis and affected blood sugar or potassium levels. Your unborn child may have an increased heartbeat or low blood sugar or lack of bowel movement. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# VENTOLIN OBSTETRIC INJECTION

**Active ingredient:** *salbutamol sulfate*

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about being given VENTOLIN OBSTETRIC INJECTION. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about being given VENTOLIN OBSTETRIC INJECTION.**

**Where to find information in this leaflet:**

- [1. Why am I being given VENTOLIN OBSTETRIC INJECTION?](#)
- [2. What should I know before I am given VENTOLIN OBSTETRIC INJECTION?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is VENTOLIN OBSTETRIC INJECTION given?](#)
- [5. What should I know when being given VENTOLIN OBSTETRIC INJECTION?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I being given VENTOLIN OBSTETRIC INJECTION?**

**VENTOLIN OBSTETRIC INJECTION** contains the active ingredient salbutamol sulfate.

**VENTOLIN OBSTETRIC INJECTION** is used to stop contractions of premature labour between weeks 24 and 33 of pregnancy.

**VENTOLIN OBSTETRIC INJECTION** 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.

This medicine is not addictive.

## **2. What should I know before I am given VENTOLIN OBSTETRIC INJECTION?**

### **Warnings**

**You should not receive VENTOLIN OBSTETRIC INJECTION if:**

- you are allergic to salbutamol sulfate, or any of the ingredients listed at the end of this leaflet.
- you are less than 24 weeks pregnant.

- you have any problem where it would not be safe to prolong the pregnancy.
- you have asthma.
- you have high calcium levels.
- you have a thyroid problem associated with pregnancy.
- you had or are having treatment for high blood pressure, including high blood pressure associated with pregnancy.
- you have pre-existing heart disease or rapid heartbeats.
- you have any bowel problems.
- 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 are having more than one baby.
- the expiry date printed on the pack has passed, or if the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can use this medicine.

### **Check with your doctor if you:**

- take any medicines for any other condition.

- are allergic (hypersensitive) to foods, dyes, preservatives or any other medicines.
- have had to stop taking this or any other asthma medicine for any reason.
- have had to stop taking this or any other medicine for treating labour in pregnancy.
- have been diagnosed with, or are being treated for, a thyroid problem.
- have been diagnosed with, or are being treated for, heart problems.
- have been diagnosed with, or are being treated for, a liver problem.
- are aware of any condition that may cause low blood potassium.
- you suffer from anxiety or panic attacks.
- have any other medical condition due to your pregnancy.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **3. What if I am taking other medicines?**

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with VENTOLIN OBSTETRIC INJECTION and affect how it works.**



**Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VENTOLIN OBSTETRIC INJECTION.**

#### **4. How is VENTOLIN OBSTETRIC INJECTION given?**

A doctor or nurse will give VENTOLIN OBSTETRIC INJECTION as an injection.

**If you have any concerns about how this medicine is to be given, talk to your doctor.**

#### **How it is given**

- VENTOLIN OBSTETRIC INJECTION must only be given by a doctor or healthcare professional who is 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 it is given VENTOLIN OBSTETRIC INJECTION should not be given for more than 48 hours at a time.**

### **If you are given too much VENTOLIN OBSTETRIC INJECTION (overdose)**

If you think that you have been given too much VENTOLIN OBSTETRIC INJECTION, you may need urgent medical attention.

Symptoms of an overdose may include:

- increased heart rate.
- significant muscle tremors.
- increased rate of breathing due to increased acid in the blood.
- **You should immediately:**
- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while being given VENTOLIN OBSTETRIC INJECTION?**

### **Things you must do**

- Remind any doctor you visit that you are being given VENTOLIN OBSTETRIC INJECTION, especially if you are about to be started on any new medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using 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.
- Discuss your pregnancy and breastfeeding with your doctor.
- Discuss your asthma management with your doctor. It is important that asthma is managed well during pregnancy and you should not stop your asthma medication without asking your doctor.

Please see Section [6. Are there any side effects?](#) for more instances in which you should contact your doctor.

### **Things you should not do**

- Do not use VENTOLIN OBSTETRIC INJECTION to treat any other complaints unless your doctor says to.

## Looking after your medicine

VENTOLIN OBSTETRIC INJECTION will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage. It should be stored below 30°C away from moisture, heat, or sunlight.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following list of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<b>Musculoskeletal and connective tissue disorders:</b> <ul style="list-style-type: none"><li>• ‘Shakiness’ of the muscles.</li><li>• Muscle cramps.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<p><b>Cardiovascular disorders:</b></p> <ul style="list-style-type: none"> <li>• High blood pressure.</li> <li>• Low blood pressure.</li> </ul> <p><b>General disorders and administration site conditions:</b></p> <ul style="list-style-type: none"> <li>• Faint or dizzy feeling.</li> <li>• Drowsiness and weakness.</li> <li>• Sweating and/or chills.</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>• Nausea or sick feeling.</li> <li>• Constipation or diarrhoea or other bowel trouble.</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• Anxious or tense feeling.</li> <li>• Headache.</li> <li>• Hyperactivity.</li> <li>• Difficulty sleeping.</li> </ul> <p><b>Hepatobiliary disorders:</b></p> <ul style="list-style-type: none"> <li>• Jaundice (yellow skin or eyes).</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Allergic reactions:</b></p> <ul style="list-style-type: none"><li>• If you have any of the following symptoms after receiving VENTOLIN OBSTETRIC INJECTION, stop receiving this medicine and tell your doctor or nurse immediately.</li><li>• Symptoms of an allergic reaction include:<ul style="list-style-type: none"><li>◦ shortness of breath.</li><li>◦ wheezing, coughing or difficulty breathing.</li><li>◦ swelling of the face, lips/mouth, tongue, or throat.</li><li>◦ rash, itching, redness, or hives on the skin.</li><li>◦ suddenly feeling weak or light headed (may lead to loss of consciousness).</li></ul></li></ul> <p><b>Skin and subcutaneous tissue disorders:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Skin rash.</li> <li>• Angioedema (sudden swelling under the skin).</li> </ul> <p><b>Respiratory disorders:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• If you feel breathless or start coughing when your medicine is given or just after, tell your doctor immediately.</li> <li>• Shortness of breath.</li> </ul> <p><b>Cardiovascular disorders:</b></p> <ul style="list-style-type: none"> <li>• You are aware of your heartbeat.</li> <li>• Heartbeat is faster than normal.</li> <li>• Heartbeat does not feel regular.</li> <li>• ‘Warm’ feeling.</li> </ul>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Loss of or reduction in blood flow (ischaemia) to the heart.</li> <li>• Increased blood flow to the extremities (peripheral vasodilation).</li> </ul> <p><b>Lactic acidosis:</b></p> <ul style="list-style-type: none"> <li>• This often affects people who are receiving high dose treatment with this medicine and in patients with an acute exacerbation of asthma.</li> <li>• Acidosis, which affects the blood, may occur due to a build-up of lactic acid.</li> </ul> <p><b>Pregnancy, puerperium and perinatal conditions:</b></p> <ul style="list-style-type: none"> <li>• Your unborn child may have an increased heartbeat.</li> <li>• Very rarely, the unborn child may have low blood sugar or lack of bowel movement.</li> </ul> <p><b>Metabolic and nutritional disorders:</b></p>	



Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Changes in blood sugar (glucose) or blood potassium levels. This can only be detected when your doctor conducts tests over time to monitor your progress.</li> </ul>	

**Tell your doctor if you notice anything else that may be making you feel unwell.**

Other side effects not listed in this document may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

## **What VENTOLIN OBSTETRIC INJECTION contains**

<b>Active ingredient</b>	salbutamol sulfate
<b>Other ingredients</b>	sodium chloride water for injections sulfuric acid

**You should not be given this medicine if you are allergic to any of these ingredients.**

## **What VENTOLIN OBSTETRIC INJECTION looks like**

VENTOLIN OBSTETRIC INJECTION liquid is either colourless or pale straw coloured, stored in clear glass ampoules. Each ampoule of VENTOLIN OBSTETRIC INJECTION contains 5 mL of liquid and provides 5 mg of salbutamol sulfate. There are 5 ampoules in a box (AUST R 12528).

## **Who distributes VENTOLIN OBSTETRIC INJECTION**

GlaxoSmithKline Australia Pty Ltd  
Level 4, 436 Johnston Street,  
Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au](http://www.gsk.com.au)

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