Patient Information Leaflet

SCHEDULING STATUS:

S4

VENTOLIN INJECTION

Salbutamol 0,5 mg/ml

Read all of this leaflet carefully before you start receiving VENTOLIN INJECTION.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.
- VENTOLIN INJECTION has been prescribed for you and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What VENTOLIN INJECTION is and what it is used for
2. What you need to know before you are given VENTOLIN INJECTION
3. How VENTOLIN INJECTION is administered
4. Possible side effects
5. How to store VENTOLIN INJECTION
6. Contents of the pack and other information.

1. What VENTOLIN INJECTION is and what it is used for:

Salbutamol is one of a group of medicines called beta-2-agonists which act on special receptor sites in the body.

VENTOLIN INJECTION can be used for two different purposes.

i. To relieve severe bronchospasm (wheeze as in asthma and chronic bronchitis).

ii. To stop premature labour.

2. What you need to know before you are given VENTOLIN INJECTION:

You should not be given VENTOLIN INJECTION:

- if you are hypersensitive (allergic) to salbutamol sulphate or the other ingredients of VENTOLIN INJECTION which are listed at the beginning of this leaflets (see section 6)
- if you are less than 22 weeks pregnant
- if you suffer from or have a known risk of developing ischaemic heart disease (disease characterised by reduced blood supply to your heart muscle, causing symptoms such as chest pain (angina))

  if 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 from vagina during pregnancy (postpartum haemorrhage), placenta is covering the birth canal or is detaching (placenta praevia), abnormal condition of pregnancy which is characterised by high blood pressure, swelling and protein in the urine (toxaemia in pregnancy) or your baby has died inside the womb).

If you are not sure whether you should receive VENTOLIN INJECTION, please discuss with your doctor before receiving this medicine.

Warnings and precautions:

Take special care with VENTOLIN INJECTION:

Tell your doctor or healthcare professional before being given the injection:

- if you have an overactive thyroid gland
- if you have high blood pressure
- if you have low blood potassium levels, as treatment with VENTOLIN INJECTION can make this condition worse

- if you suffer from heart disease with palpitations (e.g. heart valve disorder) or long-standing lung disease (e.g. chronic bronchitis, emphysema) causing an increase of blood pressure to your lungs (pulmonary hypertension)
- if you are taking beta-blocking medicines
- if you have diabetes
- if during pregnancy, your waters have broken
- if you have too much fluid in the lungs causing breathlessness (pulmonary oedema).

If any of these points apply to you, consult your doctor first before receiving VENTOLIN INJECTION.

Other medicines and VENTOLIN INJECTION:

Always tell your healthcare professional if you are taking any other medicine (this includes complimentary or traditional medicines).

Tell your doctor or nurse if you are taking:

- medicines for an irregular or fast heartbeat (such as digoxin)
- beta-blocking agents (such as atenolol or propranolol)
- xanthine medicines (such as theophylline or aminophylline)
- cortisone medicines (such as prednisolone)
- water tablets, also known as diuretics (such as furosemide)
- medicines for diabetes to reduce your blood sugar (such as insulin, metformin or glibenclamide
- other medicines for asthma.

VENTOLIN INJECTION should not be administered in the same syringe as any other medication.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before you are given VENTOLIN INJECTION.

3. How VENTOLIN INJECTION is administered:

Do not share medicines prescribed for you with any other person.

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.

It can be given to you under the skin (subcutaneously), or directly into a vein or muscle (intravenous or intramuscular route).

The usual dose is:

- Use in asthma: 500 micrograms every four hours as required by intramuscular injection or subcutaneous injection, or 250 micrograms every four hours by intravenous injection.
- Use in premature labour: 100-250 micrograms by intravenous injection.

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 may beat faster than usual
- you may feel shaky
- you may feel sick (nausea) or be sick (vomit)
- you may become restless or irritable
- you may see or hear things which are not there (hallucinations).

4. Possible side effects:

VENTOLIN INJECTION can cause side effects.

Not all side effects reported for VENTOLIN INJECTION are included in this leaflet. Should your general health worsen, or if you experience any untoward effects, while using VENTOLIN INJECTION, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects are very serious. You may need urgent medical attention:

- Some people can be allergic to VENTOLIN INJECTION. If you have any of the following symptoms soon after receiving VENTOLIN INJECTION talk to your doctor immediately:
  - swelling of eyelids, face or lips
  - lumpy skin rash or ‘hives’ anywhere on the body
  - sudden wheeziness or chest tightness
  - feeling faint and lightheaded, or collapse.
- Patients receiving VENTOLIN INJECTION for the treatment of premature labour: cough, wheezing, chest pain, shortness of breath, which may be signs of pulmonary oedema (fluid in the lungs). These side effects are less frequent. Tell your doctor immediately if you have any of these side effects.

Talk to your doctor as soon as possible if you experience any of the following.

Frequent side effects:

- your heart is beating faster or stronger than usual (palpitations)
- your heartbeat is uneven or gives extra beats
- feeling shaky
- headache
- muscle cramps.

The following side effects can also happen less frequently:

- Chest pain due to heart problems (angina). Tell your doctor, nurse or pharmacist if this occurs. Do not stop using VENTOLIN INJECTION unless told to do so.
- A condition known as lactic acidosis which may cause stomach pain, rapid breathing or shortness of breath, cold feet and hands, irregular heartbeat or thirst.
- Changes in behaviour such as restlessness and excitability.
- Being sick (vomiting) or feeling sick (nausea) can occur when VENTOLIN INJECTION is used to treat premature labour.
- A stinging or pain when the injection is given directly into the muscle.

The following could be seen in your blood test results:

- low potassium levels
- high glucose levels
- high lactic acid levels.

If any of these side effects get serious, please tell your doctor or pharmacist. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VENTOLIN INJECTION.

5. How to store VENTOLIN INJECTION:

Do not use after the date shown as 'Exp' on the carton and label.

Store at or below 30 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What VENTOLIN INJECTION contains:

Each 1 ml ampoule of VENTOLIN INJECTION contains 500 µg (micrograms) of salbutamol (as salbutamol sulphate.

The other ingredients are a sterile saline solution consisting of sodium chloride, sulphuric acid, sodium hydroxide, nitrogen and water for injections.

What VENTOLIN INJECTION looks like and contents of the pack:

The solution is colourless to very pale straw coloured and odourless. Its specific gravity and viscosity are similar to water.

1 ml ampoules in boxes of 5.

Holder of certificate of registration and manufacturer:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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