VENTOLIN INJECTION

SCHEDULING STATUS:

S4

1. NAME OF THE MEDICINE:

VENTOLIN INJECTION

Salbutamol 0,5 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Ampoules of 1 ml each of which contains salbutamol sulphate B.P. equivalent to 0,5 mg (500 µg) salbutamol.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Injection.

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

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

1. Use in Asthma:

   VENTOLIN INJECTION is indicated for the relief of severe bronchospasm associated with asthma or bronchitis and for the treatment of status asthmaticus.

2. Use in Obstetrics:

   VENTOLIN INJECTION is indicated to inhibit uncomplicated premature labour between 22 and 37 weeks of gestation in patients with no medical or obstetric contra-indication to tocolytic

therapy.

4.2 Posology and method of administration:

VENTOLIN INJECTION is to be used only under medical direction.

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

1. **Use in asthma:**

   VENTOLIN INJECTION may be administered subcutaneously, intramuscularly or intravenously.

   Intramuscular route:

   Adults – 500 µg (8 µg/kg body mass) and repeated every four hours as required.

   Subcutaneous route:

   Adults – 500 µg (8 µg/kg body mass) and repeated every four hours as required.

   Intravenous route:

   Adults – 250 µg (4 µg/kg body mass) injected slowly. If required for ease of administration VENTOLIN INJECTION may be diluted with Water for Injections B.P., Sodium Chloride Injection B.P., Sodium Chloride and Dextrose Injection B.P., or Dextrose Injection B.P. These are the only recommended diluents and it is inadvisable to administer VENTOLIN INJECTION in a syringe containing any other medication.

   NOTE: If VENTOLIN INJECTION must be given to an asthmatic patient in labour it will inhibit uterine contractions. This effect can be counteracted by administration of natural or synthetic oxytocic drugs.

2. **Use in obstetrics:**

   Treatment with VENTOLIN INJECTION should only be initiated by medical practitioners experienced in the use of tocolytic agents. Ideally, it should be carried out in facilities adequately equipped to perform continuous monitoring of maternal and foetal 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 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 VENTOLIN INJECTION (see section 4.3). This should include an adequate assessment of the patient's cardiovascular status with continuous ECG monitoring throughout treatment (see section 4.4.

VENTOLIN INJECTION may be administered as a single injection by the intravenous route. The usual recommended dose is 100 to 250 µg of VENTOLIN INJECTION. The dose may be repeated according to the response of the patient.

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. A maximum sustained maternal heart rate of 120 beats/min should not be exceeded.

Treatment should be discontinued, should signs and symptoms of pulmonary oedema or myocardial ischaemia develop (see section 4.4).

4.3 Contraindications:

VENTOLIN INJECTION is contraindicated in patients with a history of hypersensitivity to salbutamol sulphate or to any of the components of VENTOLIN INJECTION.

VENTOLIN INJECTION should not be used for threatened abortion.

VENTOLIN INJECTION, when used in the management of premature labour, is contra-indicated in the following conditions:

- at a gestational age < 22 weeks
- intrauterine foetal death, known lethal congenital or lethal chromosomal malformation

- any condition of the mother or foetus in which prolongation of the pregnancy is hazardous (including placenta praevia, antepartum haemorrhage, toxaemia of pregnancy)
- in patients with pulmonary hypertension, valvular heart disease, pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease.

4.4 Special warnings and precautions for use:

VENTOLIN INJECTION should be administered with caution in patients with thyrotoxicosis.

Increasing use of VENTOLIN INJECTION to control symptoms of asthma, indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed.

Sudden and progressive deterioration in asthma control is potentially life threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Potentially serious hypokalaemia may occur from VENTOLIN INJECTION therapy.

Particular caution is advised in acute severe asthma as hypokalaemia may be potentiated by concomitant treatment with xanthine derivatives, corticosteroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

VENTOLIN INJECTION should be administered with caution to patients with co-existing heart disease (see section 4.3).

VENTOLIN INJECTION and beta-blocking medicines should not be prescribed together.

The use of VENTOLIN INJECTION in the treatment of severe bronchospasm or status asthmaticus does not obviate the requirement for glucocorticoid steroid therapy as appropriate.

When practicable, administration of oxygen concurrently with VENTOLIN INJECTION is recommended, particularly when it is given by IV infusion to hypoxic patients.

VENTOLIN INJECTION can induce increased blood glucose levels. A diabetic patient may be unable to compensate for this and the development of keto-acidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

Lactic acidosis has been reported in association with high doses of VENTOLIN INJECTION mainly

in patients being treated for an acute asthma exacerbation. Increase in lactate levels may lead to dyspnoea and compensatory hyperventilation, which could be misinterpreted as a sign of asthma treatment failure and lead to inappropriate intensification of VENTOLIN INJECTION treatment. It is therefore recommended that patients are monitored for the development of elevated serum lactate and consequent metabolic acidosis in this setting.

In addition in obstetric use: In the treatment of premature labour, before VENTOLIN INJECTION is given to any patient with known heart disease, an adequate assessment of the patient's cardiovascular status should be made by a medical practitioner experienced in heart diseases (see section 4.3).

Tocolysis with VENTOLIN INJECTION is not recommended when membranes have ruptured or the cervix has dilated beyond 4 cm.

Increases in maternal heart rate of the order 20 to 50 beats per minute usually accompany infusion. The maternal pulse rate should be monitored and not normally allowed to exceed a sustained rate of 120 beats per minute. The effect of infusion on foetal rate is less marked but increases of up to 20 beats per minute may occur.

Maternal blood pressure may fall slightly during the infusion; the effect being greater on diastolic than on systolic pressure. Falls in diastolic pressure are usually within the range of 10 to 20 mmHg.

As maternal pulmonary oedema and myocardial ischaemia have been reported during or following treatment of premature labour with VENTOLIN INJECTION, careful attention should be given to fluid balance and cardio-respiratory function, including ECG, should be monitored continuously. If signs of pulmonary oedema or myocardial ischaemia develop VENTOLIN INJECTION should be discontinued.

4.5 Interactions with other medicines and other forms of interactions:

VENTOLIN INJECTION and beta-blocking medicines should not be prescribed together.

4.6 Fertility, pregnancy and lactation:

The safety of VENTOLIN INJECTION in pregnancy and lactation has not been established.

4.7 Effects on the ability to drive and use machines:

Not applicable.

4.8 Undesirable effects:

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000) and very rare (< 1/10 000), including isolated reports.

Clinical trials data:

Nervous system disorders:

Very common: tremor

Common: headache

Cardiac disorders:

Very common: tachycardia, palpitations

Uncommon: myocardial ischaemia*

*In the management of pre-term labour

Respiratory, thoracic and mediastinal disorders:

Uncommon: pulmonary oedema

In the management of pre-term labour VENTOLIN INJECTION has been associated with pulmonary oedema

Musculoskeletal and connective tissue disorders:

Common: muscle cramps.

Post marketing data:

Immune system disorders: anaphylactic reactions (hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse)

Metabolism and nutrition disorders: potentially serious hypokalaemia may occur, lactic acidosis

Lactic acidosis has been reported in patients receiving VENTOLIN INJECTION for the treatment of acute asthma exacerbation.

Nervous system disorders: hyperactivity, agitation

Cardiac disorders: cardiac dysrhythmias including atrial fibrillation, superventricular tachycardia and extrasystoles

Vascular disorders: peripheral vasodilatation

Gastrointestinal disorders: nausea, vomiting

In the management of premature labour, VENTOLIN INJECTION has been associated with nausea and vomiting.

Injury, poisoning and procedural complications: slight pain or stinging on intramuscular use of undiluted injection.

4.9 Overdose:

Symptoms and Signs:

The most common signs and symptoms of overdose with VENTOLIN INJECTION are beta agonist pharmacologically mediated events (refer to section 4.8).

Agitation, hallucination and irritability have been reported.

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

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

Treatment:

Consideration should be given to discontinuation of treatment and appropriate symptomatic therapy.

5. PHARMACOLOGICAL PROPERTIES:

A 10.2 Bronchodilators

5.1 Pharmacodynamic properties:

Salbutamol is a beta-adrenergic stimulant which has a selective action on the B_2-adrenoceptors throughout the body.

5.2 Pharmacokinetic properties:

Salbutamol administered intravenously has a half-life of 4-6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulphate (phenolic sulphate) which is also excreted primarily in the urine. The faeces are a minor route of excretion.

The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10 %.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

A sterile isotonic solution consisting of sodium chloride, sulphuric acid, sodium hydroxide, nitrogen and water for injections.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf-life:

36 months.

6.4 Special precautions for storage:

Store at or below 30 °C and protect from light.

Keep out of reach of children.

6.5 Nature and contents of container:

1 ml ampoules in boxes of 5.

6.6 Special precautions for disposal:

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

8. REGISTRATION NUMBER:

H/10.2.2/118

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

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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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