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:

48 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:

7 April 1976

10. DATE OF REVISION OF TEXT:

22 September 2025

GDS-21