1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

VENTEZE®-2 tablets

VENTEZE® 4 tablets

VENTEZE® SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of VENTEZE-2 contains 2 mg salbutamol as salbutamol sulphate.

Sugar free.

For full list of excipients, see section 6.1.

Each tablet of VENTEZE 4 contains 4 mg salbutamol as salbutamol sulphate.

Sugar free.

For full list of excipients, see section 6.1.

Each 5 ml of VENTEZE SYRUP contains 2 mg salbutamol as salbutamol sulphate

Preservative: Sodium benzoate 0,2 % *m/v*

Contains sweetener: Saccharin sodium 10 mg

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

VENTEZE-2 and VENTEZE 4: Tablets

VENTEZE SYRUP: Syrup

VENTEZE-2:

A round, flat, lilac tablet with bevelled edges, bisected on one side and plain on the other side. The 2 mg tablet has a diameter of 6,5 mm.

VENTEZE 4:

A round, flat, lilac tablet with bevelled edges, bisected on one side and plain on the other side. The 4 mg tablet has a diameter of 8,8 mm.

VENTEZE SYRUP: A clear orange liquid with an orange odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VENTEZE is indicated as a bronchodilator:

- in the treatment of bronchospasm associated with bronchial asthma.
- emphysema.
- chronic obstructive bronchitis.

4.2 Posology and method of administration

Posology

VENTEZE-2 and VENTEZE 4 tablets

Adults

The usual dose is 2 mg to 4 mg three or four times daily.

VENTEZE Syrup

Adults:

5 ml to 10 ml (1 to 2 measuresful) three to four times

daily.

Some patients may require dosages of up to 20 ml.

Special populations

Elderly population

Elderly patients should be given the lower dose initially.

Paediatric

The safety and efficacy of VENTEZE in children aged younger than 2 years has not yet been established.

VENTEZE-2 and VENTEZE 4 tablets

Children:

2 to 6 years: 1 mg to 2 mg three or four times daily.

6 to 12 years: 2 mg three or four times daily.

Over 12 years: Adult dose.

VENTEZE Syrup

Children:

2 to 6 years: 2,5 ml to 5 ml (½ to 1 measureful) three to

four times daily.

Over 6 years: 5 ml (1 measureful) three to four times daily.

Method of administration

For oral administration.

4.3 Contraindications

VENTEZE is contraindicated in:

- Patients with hypersensitivity to salbutamol or to any of the other excipients of VENTEZE (see section 6.1).
- Concurrent use with beta-blocking medicines.
- Hyperthyroidism.
- Cardiac disease.
- Prevention of premature labour associated with toxaemia of pregnancy or ante partum haemorrhage.
- Threatened abortion during first and second trimesters of pregnancy.
- Concurrent use with monoamine oxidase inhibitors (MAOIs) (see section 4.5).

4.4 Special warnings and precautions for use

Tolerance may develop in asthmatic patients given VENTEZE. If tolerance develops, and the patient's condition worsens, alternative or additional therapy should be instituted. The dosage of VENTEZE should not be increased in these cases.

VENTEZE should be avoided or used with care in patients undergoing anaesthesia with any halogenated anaesthetics.

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma.

Increasing use of bronchodilators indicates deterioration of asthma control. If patients find that short acting relief bronchodilator treatment becomes less medical attention must be sought.

VENTEZE causes peripheral vasodilation which may result in reflex tachycardia and increased cardiac output.

VENTEZE should be used with caution in patients with hyperthyroidism, cardiovascular disease, occlusive vascular disorders, hypertension or aneurysms.

Hyperthyroidism

VENTEZE should only be administered cautiously to patients suffering from thyrotoxicosis after careful evaluation of the benefits and risks of treatment (see section 4.3).

Constant monitoring of potassium levels in patients with severe asthma is essential, potentially serious hypokalaemia may result from beta-2 agonist therapy.

Hypokalaemia associated with high doses of VENTEZE may result in increased susceptibility to digoxin-induced cardiac dysrhythmias.

In common with other β-adrenoceptor agonists, VENTEZE can induce reversible metabolic changes such as increased blood glucose levels.

Diabetes

Administration of beta agonists is associated with a rise of blood glucose. Therefore blood glucose and lactate levels should be monitored in diabetics and diabetic treatment adjusted accordingly to meet the needs of the diabetic during tocolysis. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of ketoacidosis has been reported.

Concurrent administration of corticosteroids can exaggerate this effect.

Cardiovascular effects may be seen with sympathomimetic medications, including VENTEZE.

Respiratory indications

Patients with underlying severe heart disease (e.g. ischaemic heart disease, dysrhythmia or severe heart failure) who are receiving VENTEZE should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Tachyphylaxis with resistance may occur with prolonged use of high dosage.

Care is necessary when treating patients with closed-angle glaucoma, and in those receiving antihypertensive therapy.

It is important to avoid excessive doses as this is thought to be linked to sudden death probably due to the induction of ventricular dysrhythmias.

Salbutamol may be restricted in certain sports as it is considered to be a member of the prohibited group, Beta-2 agonists; competitors should check with the appropriate sports authorities.

4.5 Interaction with other medicines and other forms of interaction

The effects of VENTEZE are antagonised by propranolol and other β-adrenoceptor blocking medicines.

An increased risk of dysrhythmias may occur if patients are receiving digoxin, quinidine, or tricyclic antidepressants.

The effects of VENTEZE may be altered by reserpine or methyldopa.

Interaction with alpha-and beta-blocking medicines may occur.

VENTEZE may interact with monoamine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days after stopping treatment (see section 4.3).

Halogenated anaesthetics

Owing to the additional antihypertensive effect, there is increased uterine inertia with risk of haemorrhage; in addition, serious ventricular rhythm disorders due to increased cardiac reactivity, have been reported on interaction with halogenated anaesthetics. Treatment should be discontinued, whenever possible, at least 6 hours before any scheduled anaesthesia with halogenated anaesthetics (see section 4.4).

Anti-diabetics

The use of VENTEZE and other beta-agonists are associated with a rise of blood glucose which may be interpreted as an attenuation of anti-diabetic therapy; therefore individual anti-diabetic therapy may need to be adjusted.

Potassium depleting medicine

Owing to the hypokalaemic effect of beta-agonists, concurrent administration of serum potassium depleting medicine known to exacerbate the risk of hypokalaemia, such as diuretics, digoxin, methyl xanthines (e.g. theophylline) and corticosteroids, should be administered cautiously after careful evaluation of the benefits and risks with special regard to the increased risk of cardiac arrhythmias arising as a result of hypokalaemia.

4.6 Fertility, pregnancy and lactation

Pregnancy

VENTEZE should only be used during pregnancy if it is considered essential by the physician.

Breastfeeding

As VENTEZE is probably secreted in breast milk its use in nursing mothers requires careful consideration.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that VENTEZE does not adversely affect their ability to do so safely (see section 4.8).

4.8 Undesirable effects

a) Tabulated list of adverse reactions

System organ class	Frequent	Less frequent
Immune system disorders		Hypersensitivity reactions including paradoxical bronchospasm, angioedema, urticaria, hypotension, and collapse
Metabolism and nutrition disorders		Decreased appetite, altered metabolism, lactic acidosis, hypokalaemia
Psychiatric disorders		Anxiety, restlessness, insomnia, confusion, irritability, psychotic states, nervous tension
Nervous system disorders	Tremor of skeletal muscle (particularly in the hands), headache	Myoclonus
Cardiac disorders		Palpitations, tachycardia, cardiac dysrhythmias, myocardial ischaemia
Vascular disorders		Peripheral vasodilatation
Respiratory, thoracic and mediastinal disorders		Dyspnoea, pulmonary oedema
Gastrointestinal disorders		Nausea, vomiting, hypersalivation
Musculoskeletal and connective tissue disorders		Muscle cramps
Renal and urinary disorders		Difficulty in micturition, urinary retention
General disorders and administrative site conditions		Asthenia, increased sweating

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:
E-mail: Drugsafety@aspenpharma.com
Tel: 0800 118 088

4.9 Overdose

See sections 4.4 and 4.8.

Symptoms

Fine tremor of skeletal muscles, tachycardia, palpitations, hyperactivity, peripheral vasodilatation and metabolic effects including hypokalaemia.

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

Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

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

Treatment

The preferred antidote for overdosage with VENTEZE is a cardioselective beta blocking medicine, but beta blocking medicines should be used with caution in patients with a history of bronchospasm.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists.

ATC code: R03CC02

Mechanism of action

Salbutamol is a beta-adrenergic stimulant which has a selective action on bronchial beta-adreno-receptors.

5.2 Pharmacokinetic properties

Absorption

Salbutamol is readily absorbed from the gastrointestinal tract.

Distribution

The peak plasma concentration of salbutamol and its metabolites is 5,1 to 11,7 ng/ml at 2,5 to 3 hours after an oral dose of 4 mg.

Biotransformation

Salbutamol does not cross the blood brain barrier to a significant extent, but it crosses the placental barrier. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

Elimination

Salbutamol is excreted in urine in about 24 hours, with 50 % being excreted within 4 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

VENTEZE®-2 (tablets)

Calcium sulphate dihydrate, croscarmellose sodium, erythrosine aluminium lake (C.I. 45430), indigo carmine lake (C.I. 73015), magnesium stearate, maize starch

VENTEZE®-4 (tablets)

Calcium sulphate dihydrate, croscarmellose sodium, indigo carmine lake (C.I. 73015), erythrosine aluminium lake (C.I. 45430), magnesium stearate, maize starch

VENTEZE® SYRUP

Citric acid monohydrate, disodium edetate, orange flavour, saccharin sodium, sodium benzoate, sodium phosphate, xanthan gum, yellow colour (Sunset Yellow E-110 (C.I. 15985))

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

VENTEZE-2 tablets: 24 months

VENTEZE 4 tablets: 24 months

VENTEZE SYRUP 100 ml bottle: 48 months

VENTEZE SYRUP 150 ml and 500 ml bottle: 24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

VENTEZE-2:

Polypropylene securitainers in pack sizes of 100 and 500 tablets together with a foam insert or rayon, sealed with a linear low density polyethylene closure. Blister packs consisting of hard-tempered aluminium foil and clear PVC.

VENTEZE 4:

Polypropylene securitainers in pack sizes of 100 and 500 tablets together with a foam insert or rayon, sealed with a linear low density polyethylene closure. Blister packs consisting of hard-tempered aluminium foil and clear PVC.

VENTEZE SYRUP:

100 ml round amber glass bottle with a polypropylene cap with EXPE liner.

150 ml and 500 ml PVC bottles with a polypropylene cap with EXPE liner.

Not all packs and pack sizes are necessarily marketed.

7 HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8 REGISTRATION NUMBER

VENTEZE-2: M/10.2/14

VENTEZE 4: M/10.2/15

VENTEZE SYRUP: T/10.2/84

9 DATE OF FIRST AUTHORISATION

Date of registration:

VENTEZE-2: 23 November 1979

VENTEZE 4: 23 November 1979

VENTEZE SYRUP: 26 February 1986

10 DATE OF REVISION OF TEXT

06 June 2022

Die Afrikaanse Professionele Inligting is ope versoek beskikbaar.

Mediese Blitslyn: 0800 118 088

Botswana:	S2
VENTEZE-2:	B9323015
VENTEZE-4:	B9323020
VENTEZE SYRUP:	BOT0500742

Namibia:	NS2
VENTEZE-2:	90/10.2/001265
VENTEZE-4:	90/10.2/001266
VENTEZE SYRUP:	90/10.2/001270

Zimbabwe:	P.P.10
VENTEZE-2:	85/22.1.1/1921
VENTEZE-4:	85/22.1.1/1922

VENTEZE SYRUP: 93/22.1.1/2763

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