**SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE**

## SCHEDULING STATUS

S3

## PROPRIETARY NAME AND DOSAGE FORM

**VENTEZE RESPIRATOR SOLUTION**

## COMPOSITION

Each 1 ml of VENTEZE RESPIRATOR SOLUTION contains 5 mg salbutamol as salbutamol sulphate.

*Excipients:*

Benzalkonium chloride, citric acid monohydrate, disodium edetate.

Preservative:

Benzalkonium chloride 0,01 % *m/v*

## CATEGORY AND CLASS

A 10.2.1 Inhalants

## PHARMACOLOGICAL ACTION

### Pharmacodynamic properties

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

## INDICATIONS

VENTEZE RESPIRATOR SOLUTION is indicated for use in conjunction with intermittent positive- pressure ventilation, usually with oxygen enriched air, for the symptomatic relief of bronchospasm associated with chronic or acute asthma, bronchitis or other obstructive pulmonary diseases.

## CONTRAINDICATIONS

- VENTEZE RESPIRATOR SOLUTION should not be taken together with β-blocking agents.
- Hyperthyroidism and cardiac disease.
- Safety in pregnant and lactating women has not been established.
- VENTEZE RESPIRATOR SOLUTION may interact with mono-amine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days after stopping treatment.

## WARNINGS AND SPECIAL PRECAUTIONS

VENTEZE RESPIRATOR SOLUTION must not be used as an injection.

Tolerance may develop in asthmatic patients given VENTEZE RESPIRATOR SOLUTION. Tachyphylaxis with resistance may occur with prolonged use of high dosage. If tolerance develops, and the patient's condition worsens alternative or additional therapy should be instituted. The dosage of VENTEZE RESPIRATOR SOLUTION should not be increased in these cases.

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

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

Hypokalaemia associated with high doses of salbutamol may result in increased susceptibility to digitalis-induced cardiac arrhythmias.

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

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

*Effects on ability to drive and use machines*

Not known.

**INTERACTIONS**

The adverse effects of high doses of VENTEZE RESPIRATOR SOLUTION may be exacerbated by concomitant administration of high doses of corticosteroids.

The effects of VENTEZE RESPIRATOR SOLUTION are antagonised by propranolol and other β-adrenoceptor blocking agents and enhanced by aminophylline or other xanthines.

An increased risk of arrhythmias may occur if patients are receiving cardiac glycosides, quinidine, or tricyclic antidepressants. Interaction with α- and β-blocking agents may occur.

## HUMAN REPRODUCTION

Safety in pregnant and lactating women has not been established.

## DOSAGE AND DIRECTIONS FOR USE

Together with other forms of therapy, as in the treatment of status asthmaticus or other forms of severe bronchospasm, 2 ml of VENTEZE RESPIRATOR SOLUTION containing 10 mg salbutamol may be inhaled up to 4 times daily as a mist in oxygen enriched air through an intermittent positive-pressure ventilator over a period of three minutes.

Similarly, VENTEZE RESPIRATOR SOLUTION can be diluted with sterile water to contain 50 µg or 100 µg per 1 ml of salbutamol (1 in 100 or 1 in 50 dilution). This diluted solution may be administered as a mist by means of an intermittent positive-pressure ventilator at the rate of 1 to 2 mg salbutamol per hour. Adequate oxygenation is essential to avoid hypoxaemia.

## SIDE EFFECTS

VENTEZE RESPIRATOR SOLUTION may cause fine tremor of skeletal muscle (particularly the hands), palpitations and muscle cramps. Tachycardia, tenseness, headaches and peripheral vasodilation have been reported after large doses.

Anxiety, fever, restlessness, insomnia, confusion, irritability, weakness, psychotic states, decreased appetite, nausea and vomiting may occur due to the central effects of VENTEZE RESPIRATOR SOLUTION.

Difficulty in micturition and urinary retention, dyspnoea, altered metabolism, sweating and hypersalivation may occur.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Fine tremor of skeletal muscles, tachycardia, palpitations and peripheral vasodilation.

Treatment is symptomatic and supportive.

## IDENTIFICATION

The solution is clear and colourless.

## PRESENTATION

VENTEZE RESPIRATOR SOLUTION: 20 ml are packed in a type III, round, amber glass bottle and sealed with a 20 mm white, polypropylene screw cap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton together with a leaflet.

## STORAGE INSTRUCTIONS

Store at or below 25 °C and protect from light.

Any VENTEZE RESPIRATOR SOLUTION remaining in the bottle once it has been opened should not be used after a period of one month.

Solutions in nebulisers should be replaced daily.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

## REGISTRATION NUMBER

U/10.2.1/187

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE**

Date of registration: 12 August 1987

Date of the most recent amendment to the professional information as approved by the Authority: 12 August 1987

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| Botswana: BOT1001624 S2 |

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| Namibia: NS2 90/10.2.1/001269 |

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| Zimbabwe: P.P.10 92/22.1.2/2671 |

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**SUID-AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK**

**SKEDULERINGSTATUS**

**S3**

**EIENDOMSNAAM EN DOSEERVORM**

**VENTEZE RESPIRATOR SOLUTION** (oplossing)

**SAMESTELLING**

Elke 1 ml van VENTEZE RESPIRATOR SOLUTION bevat 5 mg salbutamol as salbutamolsulfaat.

*Eksipiënte:*

Bensalkoniumchloried, sitroensuur monohidraat, dinatrium edetaat.

Preserveermiddel:

Bensalkoniumchloried 0, 01 % *m/v*

**KATEGORIE EN KLAS**

A 10.2.1 Inhaleermiddels

**FARMAKOLOGIESE WERKING**

**Farmakodinamiese eienskappe**

Salbutamol is ’n β-adrenergiese stimulant met ’n selektiewe werking op brongiale β-adrenoreseptore.

## INDIKASIES

VENTEZE RESPIRATOR SOLUTION word aangedui vir die gebruik in samewerking met afwisselende positiewe drukventilasie, gewoonlik met suurstofryke lug, vir die simptomatiese verligting van brongospasma wat met chroniese of akute asma, brongitis of ander obstruktiewe longsiekte verband hou.

## KONTRA-INDIKASIES

- VENTEZE RESPIRATOR SOLUTION moet nie saam met β-blokkeringsmiddels geneem word nie.
- Hipertiroïdisme en hartsiekte.
- Veiligheid by swanger en lakterende vroue is nie vasgestel nie.
- VENTEZE RESPIRATOR SOLUTION kan met mono-amienoksidase inhibeerders interaksie hê, en moenie aan pasiënte wat sulke behandeling ontvang of binne 14 dae na die beëindiging van behandeling gegee word nie.

## WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

VENTEZE RESPIRATOR SOLUTION moet nie as ’n inspuiting gebruik word nie.

Verdraagsaamheid kan ontwikkel by asmatiese pasiënte wat VENTEZE RESPIRATOR SOLUTION ontvang. Tagifilakse met weerstand kan met verlengde gebruik van hoë dosisse voorkom. Indien verdraagsaamheid ontwikkel, en die pasiënt se toestand vererger, moet alternatiewe of addisionele behandeling ingestel word. Die dosering VENTEZE RESPIRATOR SOLUTION moenie in sulke gevalle verhoog word nie.

VENTEZE RESPIRATOR SOLUTION moet vermy word of met sorg gebruik word by pasiënte wat narkose met gehalogeneerde narkosemiddels ondergaan.

VENTEZE RESPIRATOR SOLUTION moet versigtig gebruik word by pasiënte met hipertiroïdisme, kardiovaskulêre siekte, okklusiewe vaskulêre versteurings, hipertensie of aneurismes.

Hipokalemie wat met hoë dosisse salbutamol verband hou, kan lei tot verhoogde vatbaarheid vir digitalis-geïnduseerde hart aritmieë.

Sorg is noodsaaklik wanneer pasiënte met diabetes mellitus of nou-hoek gloukoom behandel word, en by diegene wat antihipertensiewe behandeling ontvang.

Dit is belangrik om hoë dosisse te vermy aangesien dit vermoedelik verband hou met skielike sterfte, moontlik as gevolg van die induksie van ventrikulêre aritmieë.

*Effekte op die vermoë om te bestuur en masjinerie te gebruik*

Onbekend.

**INTERAKSIES**

Die newe-effekte van hoë dosisse van VENTEZE RESPIRATOR SOLUTION kan vererger word deur die meegaande toediening van hoë dosisse van kortikosteroïede.

Die effekte van VENTEZE RESPIRATOR SOLUTION word geantagoniseer deur propranolol en ander β-adrenoreseptor-blokkeringsmiddels en versterk deur aminofillien en ander xantiene.

’n Verhoogde risiko van aritmieë kan voorkom indien pasiënte hartglikosiede, kinidien of trisikliese antidepressante ontvang. Interaksies met α- en β-blokkeermiddels kan voorkom.

**MENSLIKE VOORTPLANTING**

Veiligheid in swanger en lakterende vroue is nie vasgestel nie.

**DOSIS EN GEBRUIKSAANWYSINGS**

Saam met ander vorme van behandeling, soos by die behandeling van status asthmaticus of ander vorme van ernstige brongospasma, kan 2 ml VENTEZE RESPIRATOR SOLUTION wat 10 mg salbutamol bevat, tot 4 keer daagliks as ’n mis in suurstofryke lug met behulp van ’n afwisselende positiewe drukventilator oor ’n tydperk van drie minute ingeasem word.

Soortgelyk kan VENTEZE RESPIRATOR SOLUTION met steriele water verdun word om 50 µg of 100 µg salbutamol per 1 ml te bevat (1 in 100 of 1 in 50 verdunning). Hierdie verdunde oplossing kan as ’n mis toegedien word met behulp van ’n afwisselende positiewe drukventilator teen ’n tempo van 1 mg tot 2 mg salbutamol per uur. Genoegsame oksigenasie is noodsaaklik om hipoksemie te vermy.

**NEWE-EFFEKTE**

VENTEZE RESPIRATOR SOLUTION kan fyn bewing van die skeletspier (veral die hande), palpitasies en spierkrampe veroorsaak. Tagikardie, spanning, hoofpyne en perifere vasodilatasie is al aangemeld met hoë dosisse.

Angstigheid, koors, rusteloosheid, slaaploosheid, verwardheid, prikkelbaarheid, swakheid, psigotiese toestande, verminderde eetlus, naarheid en braking kan voorkom as gevolg van die sentrale effekte van VENTEZE RESPIRATOR SOLUTION.

Moeilike urinering en urienretensie, dispnee, veranderde metabolisme, sweet en hipersalivering kan voorkom.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN**

Fyn bewing van skeletspiere, tagikardie, palpitasies en perifere vasodilatasie.

Behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE**

Die oplossing is helder en kleurloos.

**AANBIEDING**

VENTEZE RESPIRATOR SOLUTION: 20 ml word verpak in ’n tipe III, ronde, amberkleurige glasbottel en verseël met ’n 20 mm wit, polipropileen skroefdoppie met ’n uitgebreide poliëtileen voering. Die bottel word in ’n buitenste kartonhouer saam met ’n voubiljet geplaas.

**BERGINGSAANWYSINGS**

Bêre teen of benede 25 °C en beskerm teen lig.

Enige VENTEZE RESPIRATOR SOLUTION wat in die bottel oorbly nadat dit oopgemaak is, moet nie na ’n tydperk van 1 maand gebruik word nie.

Oplossings in nebuliseerders moet daagliks vervang word.

Hou in die oorspronklike verpakking totdat benodig word vir gebruik.

**HOU BUITE BEREIK VAN KINDERS.**

**REGISTRASIENOMMER**

U/10.2.1/187

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE**

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead 2191

**DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK**

Datum van registrasie: 12 Augustus 1987

Datum van mees onlangse wysigings aan die professionele inligting soos goedgekeur deur die Gesag: 12 Augustus 1987

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