1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

VENTEZE CFC FREE (inhaler)

COMPOSITION

Each actuation of VENTEZE CFC FREE delivers 100 micrograms of salbutamol as salbutamol sulphate.

Excipients:

Absolute ethanol, oleic acid, and 1,1,1,2-tetrafluoroethane

Contains alcohol: Absolute ethanol 5 % *m/m*

CATEGORY AND CLASS

A 10.2.1 Medicines acting on respiratory system. Inhalants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Salbutamol is a beta-adrenergic stimulant which has a selective action on bronchial beta-adrenoceptors and in therapeutic dosage, little or no action on cardiac-receptors.

Pharmacokinetics properties

Inhaled salbutamol has an onset of action within 1 to 5 minutes, produces significant bronchodilation within 15 minutes and effects persist for 3 to 4 hours.

Salbutamol in therapeutic doses has little effect on the cardiovascular system and less skeletal muscle tremor than oral therapy.

INDICATIONS

VENTEZE CFC FREE is indicated for use in the treatment of severe bronchospasm in:

- bronchial asthma of all types
- chronic bronchitis
- emphysema

VENTEZE CFC FREE has been found to be suitable for the relief of bronchospasm in patients with co-existing heart disease, but caution is advised.

CONTRAINDICATIONS

VENTEZE CFC FREE is contraindicated in:

- patients with a history of hypersensitivity to any of its components.
- thyrotoxicosis.
- concurrent use with beta-blocking medicines.
- pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS

Patients receiving treatment at home must be warned that if either the usual relief is diminished, or the usual duration of action is reduced they should not increase the dose or its frequency of administration but should seek medical advice immediately so that suitable

measures can be taken to combat the condition.

Fatalities have been reported in association with excessive use of inhaled sympathomimetic medication and with the home use of nebulisers. The exact cause of death is unknown but cardiac arrest following the unexpected development of a severe acute asthmatic crisis and subsequent hypoxia is suspected. It is important to avoid excessive dosing.

VENTEZE CFC FREE should be used with caution in patients with cardiovascular disorders especially ischaemic heart disease, angina, tachycardia, arrhythmias and hypertension.

VENTEZE CFC FREE should be used with caution in patients known to have received large doses of other sympathomimetic medicine.

Overdosage may cause cardiac effects. High dosages may increase the risk of serious side effects, including cardiac dysrhythmias. The risk is further aggravated if administered concomitantly with other medicines that cause hypokalaemia and cardiac dysrhythmias or in the presence of hypoxia and acidosis.

Do not exceed the recommended dosage. Seek medical advice if inhaler fails to give the usual degree of symptomatic relief or symptomatic relief within three hours. This could indicate deterioration of asthma control.

Use with caution in patients with hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to Q-T interval prolongation, hypertension and diabetes mellitus.

Beta-2 agonist therapy can cause serious hypokalaemia, principally from nebuliser and

parenteral administration. This effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics and by hypoxia in acute severe asthma. Serum potassium levels should be monitored in such cases (see INTERACTIONS).

INTERACTIONS

VENTEZE CFC FREE should be used with caution in patients undergoing anaesthesia with halothane or other halogenated anaesthetics as ventricular fibrillation may be induced. An increased risk of arrhythmias may also occur if administered concomitantly with cardiac glycosides, quinidine or tricyclic antidepressants. VENTEZE CFC FREE should not be given to patients receiving monoamine oxidase inhibitors or within 14 days of termination of monoamine oxidase inhibitor therapy.

Particular caution is advised in acute severe asthma as the effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. VENTEZE CFC FREE and beta-blocking drugs such as propranolol should not be prescribed together.

Concomitant administration of salbutamol and other beta-2 agonists with corticosteroids, diuretics, or xanthines increase the risk of hypokalaemia, and monitoring of potassium concentrations is recommended in severe asthma.

HUMAN REPRODUCTION

Safety for the use in pregnant and lactating women has not been established.

DOSAGE AND DIRECTIONS FOR USE

One or two inhalations, repeated every four hours if required.

Increasing use of VENTEZE CFC FREE may be a sign of worsening asthma (see WARNINGS AND SPECIAL PRECAUTIONS).

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

VENTEZE CFC FREE acts rapidly and may be used when necessary to relieve acute dyspnoea. Doses may be taken prophylactically before exertion to prevent exercise-induced asthma.

ILLUSTRATION ON THE USE OF VENTEZE CFC FREE INHALER

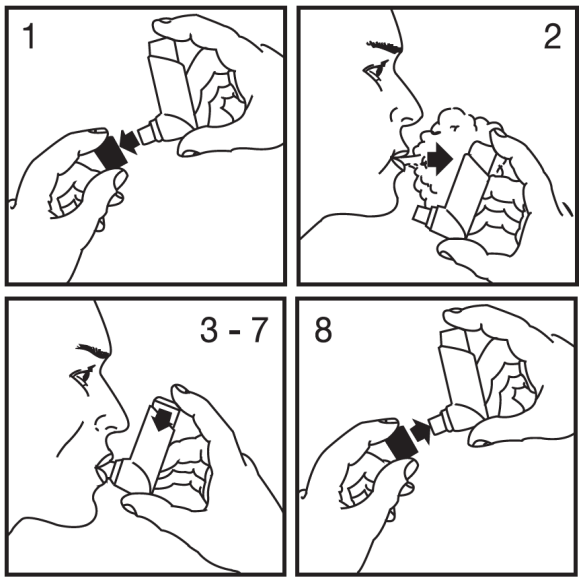
1. Remove the cover from the mouthpiece and shake the inhaler well.
2. Take a deep breath then breathe out fully, until no more air can be expelled from the lungs.
3. Holding the inhaler as illustrated (*) place the mouthpiece well into your mouth over the tongue and close your lips tightly around it.
4. Breathe in deeply and as you do so press the metal canister down firmly. This action delivers a measured amount of medication.
5. Relax the pressure on the metal canister.
6. Remove the mouthpiece from your mouth while holding your breath for a few seconds, then breathe out slowly.
7. Wait for at least one minute then repeat steps 3 to 6. Only repeat these steps if your physician has advised you to.
8. Replace the cap on the mouthpiece to protect it from dirt and dust.

(*) If difficulty is experienced in holding the inhaler and depressing the canister, both hands may be used; the two forefingers on the top and both thumbs beneath the mouth piece.

To clean: Periodic cleaning of the inhaler is recommended. Remove the canister from the inhaler unit. Rinse the inhaler in warm water, dry thoroughly and replace the canister.

Directions for use with children:

Young users of the VENTEZE CFC FREE inhaler may need assistance. Mothers should hold the inhaler, while the steps detailed above are followed. Care should be taken to depress the canister at the exact moment that the child inhales (see step 4).



SIDE EFFECTS

The following side effects have been reported with VENTEZE CFC FREE:

Cardiac disorders:

More frequently reported: tachycardia

Rarely reported: palpitations

Vascular disorders:

Have been reported (frequency unknown): peripheral vasodilation and a compensatory small increase in heart rate

Renal and urinary disorders:

Have been reported (frequency unknown): difficulty in micturition, urinary retention

Nervous system disorders:

More frequently reported: nervousness, headaches and tremor, fine tremor of skeletal muscle (particularly the hands)

Less frequently reported: dizziness

Rarely reported: fatigue, restlessness, insomnia

Have been reported (frequency unknown): sweating, fear, confusion, tenseness and central nervous system stimulation

Gastrointestinal disorders:

Less frequently reported: mouth and throat irritation

Rarely reported: nausea, vomiting

Have been reported (frequency unknown): loss of appetite, hypersalivation

Metabolism and nutrition disorders:

Rarely reported: potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration. It is recommended that serum potassium levels are monitored in such situations

Have been reported (frequency unknown): altered metabolism, hyperglycaemia

Respiratory disorders:

Rarely reported: dyspnoea. The potential for paradoxical bronchospasm should be kept in mind. If it occurs, the preparation should be discontinued immediately, and alternative therapy instituted

Musculoskeletal disorders:

Rarely reported: muscle cramps

Rarely, hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse have been reported

Beta-2 agonists may cause hyperactivity in children.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See WARNINGS AND SPECIAL PRECAUTIONS.

Treatment

Treatment is supportive and symptomatic.

The preferred antidote for salbutamol overdosage is a cardio-selective beta blocking agent. In general, beta-blocking agents should be used with caution in patients with a history of bronchospasm. Hypokalaemia may occur following overdosage with salbutamol. Serum potassium levels should be monitored.

IDENTIFICATION

A suspension of white powder.

PRESENTATION

The micronised salbutamol suspension is packed into a silver aluminium aerosol canister fitted with a silver aluminium aerosol metered dosing valve. A one-piece blue polypropylene oral adapter that fits over the aluminium canister covers the aluminium canister. The oral adapter mouthpiece is closed with a dark blue polypropylene adapter cap that fits over the adapter mouth piece. Each complete unit delivers 200 metered doses.

The inhaler is packed in an outer cardboard carton with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C away from direct sunlight or heat.

Do not freeze.

This is a pressurised canister: Do not puncture, break or burn, even when apparently empty.

Keep in the original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A39/10.2.1/0154

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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

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