1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

VENTEZE-2 tablets

salbutamol as salbutamol sulphate

Sugar free

VENTEZE 4 tablets

salbutamol as salbutamol sulphate

Sugar free

VENTEZE SYRUP 2 mg/5 ml

salbutamol as salbutamol sulphate

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

Contains sweetener: Saccharin sodium 10 mg

Sugar free

Read all of this leaflet carefully because it contains important information for you

VENTEZE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use VENTEZE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VENTEZE with any other person.
- Ask your pharmacist if you need more information or advice.

- You must see a doctor if your symptoms worsen or do not improve after 10 days

What is in this leaflet

1. What VENTEZE is and what it is used for
2. What you need to know before you take VENTEZE
3. How to take VENTEZE
4. Possible side effects
5. How to store VENTEZE
6. Contents of the pack and other information

1. What VENTEZE is and what it is used for

VENTEZE contains the active substance salbutamol.

VENTEZE belongs to a group of medicines called selective beta-2-adrenergic agonists, which can be used to relax the muscles of the airways. VENTEZE is used in the following conditions:

- Bronchial asthma
- Emphysema
- Chronic obstructive bronchitis

2. What you need to know before you take VENTEZE

Do not take VENTEZE:

- If you are allergic (hypersensitive) to salbutamol or to any of the inactive ingredients (see WHAT VENTEZE CONTAINS).
- If you are taking a medicine called a beta-blocker (used to the treatment of high blood pressure or heart disorders).
- If you have an overactive thyroid gland.
- If you have a heart disorder.

- If you are taking a medicine called a monoamine oxidase inhibitor (used in the treatment of mood disorders such as depression), or if you have stopped it within the last 14 days.
- Threatened abortion (potential miscarriage) during the first 6 months of pregnancy.

VENTEZE should not be used to prevent premature labour during the first or second trimesters of pregnancy.

Warnings and precautions

Take special care with VENTEZE:

- Your body may develop a tolerance (get used to) to VENTEZE after continued use. If your asthma gets worse, consult your doctor for additional or other treatment.
- If you are about to undergo an operation where you will be put to sleep during the operation.
- If you have high blood pressure.
- If you have an aneurysm (abnormal widening or ballooning of a portion of an artery due to weakness in the wall of the blood vessel).
- If you have diabetes (high blood sugar).
- If you have an eye disorder called glaucoma.
- If you have a heart rhythm disorder.
- If you participate in certain sports where the use of VENTEZE may be prohibited.
- If you feel that the relief from taking VENTEZE becomes less, this may indicate that your asthma is not under control. Please consult your doctor for additional or other treatment.

Children

There is no experience with VENTEZE in children younger than 2 years.

Other medicines and VENTEZE

Always tell your healthcare provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

- Beta-blockers (medicines used to treat high blood pressure or heart disorders).
- Corticosteroids (used to treat conditions with pain, swelling and inflammation).
- Diuretics (water tablets).
- Other medicines used to treat asthma (such as aminophylline or theophylline).
- Certain medicines used to treat heart disorders (such as digoxin or quinidine).
- Monoamine oxidase inhibitors or tricyclic antidepressants (used to treat mood disorders such as depression) (see DO NOT TAKE VENTEZE).
- High blood pressure medicines (such as reserpine and methyldopa).
- Anti-diabetic medicines.

Taking VENTEZE with food and drink

VENTEZE may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking VENTEZE.

Driving and using machines

VENTEZE can cause weakness or confusion in some people. If this happens, you should not drive, use machinery or perform any tasks that require concentration until you are certain that VENTEZE does not adversely affect your ability to do so safely (see POSSIBLE SIDE EFFECTS).

It is not always possible to predict to what extent VENTEZE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VENTEZE affects them (see section 4).

3. How to take VENTEZE

Do not share medicines prescribed for you with any other person.

Always take VENTEZE exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is :

VENTEZE-2 and VENTEZE 4 tablets

Adults:

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

Elderly patients will be given a lower dose initially.

Children:

2 to 6 years: 1 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 to 5 ml (½ to 1 measureful) three to four times daily.

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

Adults:

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

If you take more VENTEZE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VENTEZE

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take VENTEZE at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VENTEZE can have side effects.

Not all side effects reported for VENTEZE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VENTEZE, please consult your healthcare provider for advice.

If any of the following happens, stop taking VENTEZE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to VENTEZE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Low blood pressure (light-headedness, dizziness, and fainting),
- anxiety, restlessness, trouble sleeping, confusion, irritability, nervousness,
- changes in your mental state,
- irregular or higher than normal heartbeat,
- difficulty breathing,
- tremors (shaking), particularly in the hands.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.

Less frequent side effects:

- Hives,
- decreased appetite,
- nausea (feeling sick), vomiting (being sick),
- increased saliva in your mouth, increase sweating,
- muscle cramps,
- difficulty in urination, urinary retention,
- weakness.

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, pharmacist or nurse. You can also report side effects to:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of VENTEZE.

5. How to store VENTEZE

Store all medicines out of reach of children.

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

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label or carton.

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 VENTEZE contains:

VENTEZE-2:

The active substance is 2 mg salbutamol equivalent to salbutamol sulphate.

The other ingredients are calcium sulphate dihydrate, croscarmellose sodium, erythrosine aluminium lake (C.I. 45430), indigo carmine lake (C.I. 73015), magnesium stearate, maize starch.

Sugar free

VENTEZE 4:

The active substance is 4 mg salbutamol as salbutamol sulphate.

The other ingredients are calcium sulphate dihydrate, croscarmellose sodium, indigo carmine lake (C.I. 73015), erythrosine aluminium lake (C.I. 45430), magnesium stearate, maize starch.

Sugar free.

VENTEZE SYRUP:

The active substance is 2 mg salbutamol as salbutamol sulphate per 5 ml.

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

Preservative:

Sodium benzoate 0,2 % *m/v*

Contains sweetener: Saccharin sodium 10 mg

Sugar free.

What VENTEZE looks like and contents of the pack

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.

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.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Registration number

VENTEZE-2: M/10.2/14

VENTEZE 4: M/10.2/15

VENTEZE SYRUP: T/10.2/84

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 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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