

Ventimax CFC Free (36/10.2.1/0393)

Each metered dose contains salbutamol sulphate equivalent to 100 µg salbutamol.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

VENTIMAX CFC FREE 100 µg metered dose inhaler.

Salbutamol sulphate

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

VENTIMAX CFC FREE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use VENTIMAX CFC FREE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VENTIMAX CFC FREE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What VENTIMAX CFC FREE is and what it is used for

Ventimax CFC Free (36/10.2.1/0393)

Each metered dose contains salbutamol sulphate equivalent to 100 µg salbutamol.

Active ingredient in VENTIMAX CFC FREE is Salbutamol sulphate.

Each metered dose VENTIMAX CFC FREE contains salbutamol sulphate equivalent to 100 µg salbutamol.

VENTIMAX CFC FREE inhaler is used for the treatment of bronchospasm, such as (inflammatory disease of the airways) asthma and chronic bronchitis or emphysema.

2. What you need to know before you use VENTIMAX CFC FREE

Do not use VENTIMAX CFC FREE:

- if you are hypersensitive (allergic) to salbutamol or any of the other ingredients of VENTIMAX CFC FREE.
- if you suffer from thyrotoxicosis (a condition in which the thyroid gland produces excess thyroid hormone (thyroxine) which results in effects on the whole body).
- concurrent use with medicine called beta-blocking agents such as propranolol (medicine sometimes used for heart palpitations).
- during premature labour and a threatened abortion.

Warnings and precautions

Special care should be taken with VENTIMAX CFC FREE if:

- If the usual effect of the inhaler is diminished and you are using the inhaler more often than previous, you should speak to your doctor immediately.
- If you required long term treatment with VENTIMAX CFC FREE you should, you should be checked up regularly.
- If acute asthma attacks are treated, because increased serum lactate and lactic acidosis have been reported after the use of high doses of VENTIMAX CFC FREE. This effect is reversible when the salbutamol dose is reduced.

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- If you suffer from thyroid problems, diabetes, serious heart disease, fast irregular heart rhythms or high blood pressure.
- If you are using non selective beta blocking drugs such as propranolol, because paradoxical bronchospasm can occur.
- Bronchodilators such as salbutamol in VENTIMAX CFC FREE should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment as the condition is potentially life-threatening.
- Patients with severe or unstable asthma will also require inhaled or oral corticosteroid therapy.
- Failure to respond promptly or fully to VENTIMAX CFC FREE signals a need for urgent medical advice and treatment.
- If your breathing or wheezing gets worse straight after using VENTIMAX CFC FREE, stop using it immediately and tell your doctor as soon as possible.
- VENTIMAX CFC FREE should be used with caution in patients with cardiovascular disorders such as heart disease, chest pains, fast or irregular heartbeat or high blood pressure.

Other medicines and VENTIMAX CFC FREE

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines.)

If you are having treatment that requires a general anaesthetic, please tell your anaesthetist that you are taking VENTIMAX CFC FREE. Do not use this medicine for at least six hours before the intended anaesthetic.

The following medication can increase your chances of developing side effects of the heart when used together with VENTIMAX CFC FREE

- halothane or other halogenated anaesthetics.
- digoxin, quinidine or tricyclic antidepressants (amitriptyline or trazodone).

The following medication may influence the effect of VENTIMAX CFC FREE:

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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 health care provider for advice before using VENTIMAX CFC FREE.

Safety and efficacy for use of VENTIMAX CFC FREE during pregnancy and breastfeeding have not been established.

Driving and using machines

VENTIMAX CFC FREE may have an effect on the ability to drive or operate machinery because it may cause dizziness, light-headedness or make you feel tired. Therefore you are advised to first use your VENTIMAX CFC FREE to ensure that you do not experience any of these undesirable effects before driving or using machinery.

3. How to use VENTIMAX CFC FREE

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

Always use VENTIMAX CFC FREE exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are unsure.

If you have the impression that the effect of VENTIMAX CFC FREE is too strong or too weak, tell your doctor or pharmacist.

1. Remove the mouthpiece cover by gently squeezing the sides of the cover and check the mouthpiece inside and outside to see that it is clean.
2. Shake the inhaler well.
3. Hold the inhaler upright between fingers and thumb with your thumb on the base below the mouthpiece.
4. Place the mouthpiece in your mouth between your teeth and close your lips around it, but do not bite it. Just after starting to breathe in through your mouth press down on the top of the inhaler to release salbutamol, while still breathing in steadily and deeply.

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5. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.
6. If you are to take further puffs keep the inhaler upright and wait about half a minute before repeating steps 2 to 5.

The mouthpiece cover is replaced by firmly pushing and snapping the cap into position.

Important:

Do not rush stages 4 and 5. It is important that you start to breathe in as slowly as possible just before operating your inhaler. Practise in front of a mirror for the first few times. If you see “mist” coming from the top of your inhaler or the sides of your mouth you should start again from step 2. If your doctor has given you different instructions for using your inhaler, please follow them carefully.

Your inhaler should be cleaned at least once a week:

1. Pull the canister out of the plastic casing of the inhaler and remove the mouthpiece cover.
2. Wipe the plastic casing and mouth piece with a damp cloth and leave to dry.
3. Replace the canister and mouthpiece cover.
4. Do not put the metal canister into water.

If you use more VENTIMAX CFC FREE than you should

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

If you forget to use VENTIMAX CFC FREE

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next inhalation at the usual time.

4. Possible side effects

VENTIMAX CFC FREE can have side effects.

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to 100 µg salbutamol.

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

If any of the following happens, stop using VENTIMAX CFC FREE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouths 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 allergic reaction to VENTIMAX CFC FREE. 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:

- angioedema (swelling in deep layers of the skin)
- urticaria (rash of round, red welts on skin that itch intensely)
- bronchospasm (narrowing of the airways)
- hypotension and collapse (low blood pressure and fainting)
- hypokalaemia (low potassium levels in the blood serum)
- increased serum lactate and acidosis lactic (overproduction of lactic acid)
- palpitations (rapid, strong or irregular heartbeat)
- tachycardia (abnormal rapid heartrate)
- cardiac arrhythmia (electrical impulses that coordinate your heartbeats do not work properly, causing your heart to beat too fast, too slow or irregularly)

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- myocardial ischaemia (blood flow to your heart is reduced, preventing the heart muscle from receiving enough oxygen.
- peripheral vasodilation (widening of your blood vessels)

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
- tenseness
- tremor muscle
- dizziness

Less frequent side effects:

- sleep disturbances
- hallucinations
- hyperactivity in children
- insomnia (sleeplessness)
- throat and mouth irritation
- nausea and vomiting
- dry and sore mouth
- pruritus (severe itching of the skin)
- myalgia (pain in a muscle or group of muscles)
- muscle cramps
- fine tremor (particularly of the hand)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications. By reporting side effects, you can help provide more information on the safety of VENTIMAX CFC FREE.

5. How to store VENTIMAX CFC FREE

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C
- Avoid storage in direct sunlight or heat
- Do not refrigerate (2-8 °C). Protect from freezing.
- Do not use the inhaler after the expiry date printed on the canister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
- WARNING: This canister is pressurised. Do not puncture or burn it even when empty.

6. Contents of the pack and other information

What VENTIMAX CFC FREE contains

The active is salbutamol sulphate. A metered aerosol inhaler, delivering 100 µg of salbutamol per inhalation.

The other ingredients are anhydrous ethanol and hydrofluoroalkane-134a (HFA-134a).

What VENTIMAX CFC FREE looks like and content of the pack

A metered aerosol inhaler, delivering 100 µg of salbutamol per inhalation in a standard pale blue polypropylene actuator with a dark blue polypropylene cap. Each canister provides 200 inhalations.

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Aerosol for inhalation, supplied in a pressurised can. Absence of external damage, corrosion or leakage.

Holder of Certificate of Registration

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