

**Scheduling Status:**

**S2**

## **PROVENTIL, 100 µg, Pressurised metered-dose inhaler Salbutamol sulphate**

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

- Keep this leaflet. You may need to read it again.
- Do not share PROVENTIL with any other person.
- Ask your healthcare 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 PROVENTIL is and what it is used for
2. What you need to know before you use PROVENTIL
3. How to use PROVENTIL
4. Possible side effects
5. How to store PROVENTIL
6. Contents of the pack and other information

**1. What PROVENTIL is and what it is used for:**

PROVENTIL contains salbutamol sulphate equivalent to salbutamol, which is one of a group of medicines called fast acting bronchodilators.

Salbutamol relaxes the muscles in the walls of the air passages in the lungs. This helps to open up the airways and helps to relieve chest tightness, wheezing and cough, so you can breathe more easily.

PROVENTIL is used to ease breathing problems in asthma and other chest illnesses.

**2. What you need to know before you use PROVENTIL:**

Do not use PROVENTIL:

- If you are hypersensitive (allergic) to salbutamol sulphate or any of the other ingredients of PROVENTIL (listed in section 6).
- If you unexpectedly go into early labour (premature labour) or threatened abortion.

**Warnings and precautions:**

Special care should be taken with PROVENTIL:

- If you have an overactive thyroid gland
- If you have a history of heart problems such as an irregular or fast heartbeat, chest pain, high blood pressure
- If you are using any medicine that mimics the sympathetic nervous system
- If you are taking beta blocking medicines, such as propranolol
- If your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your doctor may start or increase a medicine to control your asthma such as an inhaled corticosteroid
- If you are also taking xanthine derivates (such as theophylline) or steroids to treat asthma since it may lead to low potassium blood levels
- If you are also taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition
- If your breathing or wheezing gets worse. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator. PROVENTIL should be discontinued immediately, your doctor should assess you, and if necessary, a different fast-acting bronchodilator should be prescribed to you for on-going use.
- If you take part in competitive sport activities. The use of salbutamol as contained in PROVENTIL may lead to a positive test for a prohibited substance.

#### **Other medicines and PROVENTIL**

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

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

- Non-selective beta-2-blocking medicines e.g. propranolol
- Medicines for an irregular or fast heartbeat
- Tricyclic antidepressants such as amitriptyline
- Mono-amine oxidase inhibitors such as rasagiline, selegiline or tranylcypromine for the treatment of depression. Tell your doctor if you have taken your last dose less than 14 days ago.

PROVENTIL should be used with caution if you are undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics.

#### **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 using PROVENTIL.

### **Driving and using machines**

It is not always possible to predict to what extent PROVENTIL may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which PROVENTIL affects you.

### **PROVENTIL contains alcohol**

PROVENTIL contains a small amount of alcohol (ethanol). Each actuation (puff) from your inhaler contains about 4,32 mg of ethanol.

### **3. How to use PROVENTIL:**

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

Always use PROVENTIL 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 not sure.

PROVENTIL produces a fine mist which you must inhale into your lungs. Make sure that you know how to use the inhaler properly. The instructions are given later on in this leaflet. If you have any problems ask your doctor, nurse or pharmacist. PROVENTIL must be breathed in through the mouth.

Use one or two inhalations, repeated four-hourly if required. The bronchodilator effect of each administration of PROVENTIL lasts for at least four hours and more frequent use should be unnecessary.

You must not inhale more puffs, or use your inhaler more often, than the doctor told you to.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

### **After using your PROVENTIL**

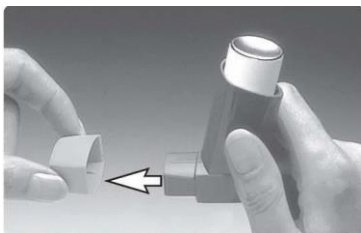
- If your breathing or wheezing gets worse straight after using PROVENTIL, stop using it immediately and tell your doctor as soon as possible.
- If the relief of wheezing or chest tightness is not as good as usual or does not last for as long as usual, tell your doctor as soon as possible. Your chest condition may be getting worse and you may need an extra medicine.
- If you need to use your PROVENTIL much more often than normal, see your doctor as soon as possible.

### **Instructions for use of your PROVENTIL:**

#### *Testing your Inhaler:*

Before using for the first time remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release two puffs into the air to make sure that it works. If it has not been used for several days shake it well and release one puff into the air to make sure that it works.

*Using your inhaler:*



1. Remove the mouthpiece cover by gently squeezing the sides of the cover.

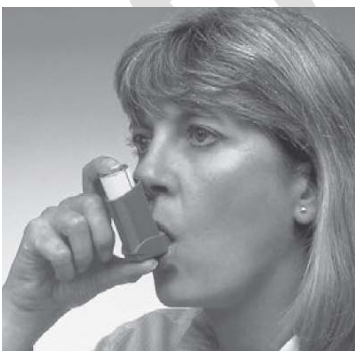


2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.

3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.



5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.



6. 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.



7. 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.
8. If you are to take further puffs keep the inhaler upright and wait about half a minute before repeating steps 3 to 7.
9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

**IMPORTANT:**

Do not rush Steps 5, 6 and 7. 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 the inhaler or the sides of your mouth you should start again from step 2.

If your doctor has been given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

*Cleaning:*

Your inhaler should be cleaned at least once a week.

1. Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly under warm running water.
3. Dry the actuator THOROUGHLY inside and out.
4. Replace the metal canister and mouthpiece cover.

**DO NOT PUT THE METAL CANISTER INTO WATER.**

**If you use more PROVENTIL than you should**

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

*The most frequent signs and symptoms of overdose with PROVENTIL are:*

Your heart beating faster than usual, you feel anxious, hallucinate (seeing or hearing things which are not there). You may also feel shaky or notice changes in your behaviour such as restlessness or irritability (see section “Possible side effects”).

Low potassium levels in your blood (hypokalaemia) may occur following overdose with PROVENTIL. The potassium levels in your blood should be monitored.

#### **If you forget to take PROVENTIL**

If you forget to inhale a dose, inhale the next dose when it is due, or if you become wheezy.

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

#### **4. Possible side effects:**

PROVENTIL can have side effects.

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

If any of the following happens, stop taking PROVENTIL 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 PROVENTIL. 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:

- your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- your heartbeat is uneven or it gives an extra beat
- chest pains due to heart problems

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*

- feeling shaky
- headache

*Less frequent side effects*

- a low level of potassium in your blood (seen in blood results)
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability
- increased blood flow to your extremities (peripheral dilatation)
- mouth and throat irritation
- muscle cramps
- stomach pain, rapid breathing or shortness of breath, cold feet and hands, irregular heartbeat, thirst or nervousness (a condition called lactic acidosis)
- an increase in wheezing

*Side effects with unknown frequency*

- nervousness or fear
- tiredness
- dizziness and confusion
- trouble sleeping
- loss of appetite
- being sick (vomiting) or feeling sick (nausea)

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 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 PROVENTIL.

**5. How to store PROVENTIL:**

Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

Protect from frost or direct sunlight. If the inhaler gets very cold, take the metal canister out of the plastic case and warm it up in your hands for a few minutes before use. Never use anything else to warm it up.

The canister is pressurised and should not be punctured or burnt even if it seems empty.

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

## **6. Contents of the pack and other information:**

### **What PROVENTIL contains:**

The active ingredient is salbutamol sulphate.

The other ingredients are dehydrated alcohol, HFA-134a (norflurane) and oleic acid.

### **What PROVENTIL looks like and contents of the pack:**

PROVENTIL is a pressurised metered-dose inhaler containing a homogeneous suspension.

PROVENTIL is a metered aerosol comprising an aluminium canister, fitted with a metering valve, delivering salbutamol sulphate equivalent to 100 µg salbutamol per inhalation with a specially designed actuator with dust cap. Each canister delivers 200 puffs.

This is then packed inside a carton containing a leaflet.

### **Holder of Certificate of Registration:**

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