

## Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed according to a physician's prescription only

# Ventolin™ Inhaler CFC Free

## Salbutamol (as sulfate) 100 mcg/dose

List of the additional ingredients listed in section 6.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

### 1. What is the medicine intended for?

Ventolin Inhaler contains a medicine called salbutamol. This belongs to a group of medicines called fast acting bronchodilators.

Ventolin Inhaler is used to relieve asthma symptoms and to prevent them in those circumstances recognized to trigger an attack (e.g. exercise or allergen exposure).

**Therapeutic group:** Selective  $\beta_2$  adrenoceptor agonist.

Ventolin Inhaler contains an ingredient called HFA 134a. This is less harmful to the environment than older inhalers. Older inhalers may taste differently to Ventolin Inhaler. This will make no difference to how your medicine works.

### 2. Before using the medicine

#### Do not use the medicine:

- If you are sensitive (allergic) to salbutamol sulfate or to any of the additional ingredients contained in the medicine as listed in section 6.
- In cases of unexpected early labour (premature labour) or threatened abortion.

#### Special warnings regarding the use of the medicine

**Talk to your physician or pharmacist before taking Ventolin Inhaler if:**

- you have a history of heart problems such as an irregular or fast heartbeat or angina pectoris.
- you have an overactive thyroid gland.
- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). In order to control your asthma, your physician may start or increase treatment with medicines such as inhaled corticosteroids.
- you have high blood pressure.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), which sometimes used to treat high blood pressure or a heart condition.

**If you are taking, have recently taken or might take other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist.**

Especially inform the physician or the pharmacist if you are taking:

- medicines for an irregular or fast heartbeat (especially from the beta blockers group such as propranolol)
- other medicines for your asthma.

#### Using the medicine and food

You can use Ventolin Inhaler at any time of day, with or without food.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.

#### Driving and using machines

Ventolin Inhaler is not likely to affect you being able to drive or use any tools or machines.

### 3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

The dosage and treatment will be determined only by the physician. The usual dosage is:

#### Adults and adolescents aged 12 years and over

- to relieve asthma - one or two puffs.
- to prevent asthma - two puffs 10-15 minutes before exercise or exposure to allergens.
- for regular treatment - two puffs up to 4 times a day.
- the maximum dosage is 8 puffs in a 24 hour period.

#### Children under 12 years of age

- to relieve asthma - one puff. The dose may be increased up to two puffs if required.

- to prevent asthma - one puff 10-15 minutes before exercise or exposure to allergens. Two puffs if required.
- for regular treatment - two puffs up to 4 times a day.
- the maximum dosage is 8 puffs in a 24 hour period.
- you may find a spacer device, with or without a face mask, useful if you have to give Ventolin Inhaler to a baby or a child under 5 – speak to your physician if you think you might need one of these.

#### Do not exceed the recommended dose

Follow the **Instructions for use** at the end of the leaflet.

**If you accidentally have taken a higher dosage** you should talk to a physician as soon as possible.

The following effects may happen:

- your heart beating faster than usual
- you feel shaky
- hyperactivity.

These effects usually wear off in a few hours.

#### If you forgot to take the medicine

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the forgotten dose.
- Do not take a double dose to make up for a forgotten dose.

Persist with the treatment as recommended by the physician.

#### If you stop taking the medicine

Do not stop taking Ventolin Inhaler without talking to your physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

### 4. Side effects

**If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately and tell your physician as soon as possible.**

As with any medicine, use of Ventolin Inhaler may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

The following side effects may happen with this medicine:

**Allergic Reactions** (very rare, may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Ventolin Inhaler and see a physician straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

#### Refer to the physician as soon as possible if:

- you feel 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
- you may feel your heartbeat is uneven or it gives an extra beat
- these may affect up to 1 in 10 people (common).

If any of these happen to you, talk to your physician as soon as possible. **Do not stop using this medicine unless told to do so.**

#### Additional side effects

Tell your physician if you have any of the following side effects which may also happen with this medicine:

**Common side effects** (may affect up to 1 in 10 people)

- feeling shaky
- headache.

**Uncommon side effects** (may affect up to 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

**Rare side effects** (may affect up to 1 in 1,000 people)

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

**Very rare side effects** (may affect up to 1 in 10,000 people)

- changes in sleep patterns and changes in behavior, such as restlessness and excitability.

**The following side effects can also happen but the frequency of these are not known:**

- chest pain, due to heart problems such as angina pectoris. Tell your physician or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

If a side effect has appeared, if any of the side effects get worse or when you suffer from side effect that has not been mentioned in the leaflet, you should consult the physician.

**If you think this medicine is not working well enough for you**

If your medicine does not seem to be working as well as usual, talk to your physician as soon as possible. Your breathing problem may be getting worse and you may need a different medicine. Do not take extra doses of Ventolin Inhaler unless your physician tells you to.

#### Reporting of suspected adverse reactions

Adverse events can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" that is located on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which refers to on-line form for adverse events reporting, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Store at a temperature below 30°C. Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Don't use anything else to warm it up.
- The metal canister is pressurised. Do not puncture, break or burn it even when apparently empty.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

### 6. Additional information

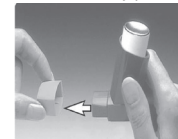
- In addition to the active ingredient the medicine also contains: HFA 134a.
- What does the medicine look like and what is the content of the package: Ventolin Inhaler comprises an aluminium alloy canister sealed with a metering valve, actuator and dust cap.
- Each canister contains 200 doses of 100 micrograms of salbutamol.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Wellcome S.A., Burgos, Spain.
- This leaflet was checked and approved by the Ministry of Health in: November 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 113-25-29560.

#### Instructions for use:

- Ventolin Inhaler produces a fine mist, which you inhale through your mouth into your lungs. Your physician, nurse or pharmacist should show you how to use your inhaler. If you are not sure ask your physician, nurse or pharmacist.
- Each Inhaler canister provides 200 doses.

Do not use your inhaler more often than the physician told you to. Tell your physician if your medicine does not seem to be working as usual, as your breathing problem may be getting worse and you may need a different medicine.

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



#### Testing your inhaler

**1.** When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

**2.** To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air. If you have not used the inhaler for 5 days or more, shake it well and release two puffs of medicine into the air.

#### Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

**1.** Stand or sit upright when using your inhaler.

**2.** Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.



**3.** Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.



5. Place the mouthpiece in your mouth between your teeth. Close your lips around the mouthpiece. Do not bite.



6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.



7. Hold your breath, take the inhaler from your mouth and your finger from the top of the canister. Continue holding your breath for a few seconds, or as long as is comfortable.

8. If your physician has told you to take two puffs, wait about half a minute before you take another puff and repeat steps 3 to 7.

9. After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Young children may need their parents help in operating the inhaler. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together. You may find a spacer device, with or without a face mask, useful if you have to give Ventolin Inhaler to a baby or a child under the age of 5 – speak to your physician if you think you might need one of these.

Older children or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the canister and both thumbs on the bottom below the mouthpiece. Your physician or pharmacist will be able to advise you.

### **Cleaning your inhaler**

To stop your inhaler blocking, it is important to clean it at least once a week.

To clean your inhaler:

- Remove the metal canister from the plastic casing of the inhaler and remove the mouthpiece cover.
- Rinse the plastic casing thoroughly under warm running water.
- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister into the plastic casing and put on mouthpiece cover.

Do not put the metal canister in water.