

This medicine is dispensed with a doctor's prescription only

Qvar® 50, 100 Autohaler® Inhaler CFC-free

Qvar® 50

Autohaler® Inhaler
CFC-free

Composition

Each actuation delivers:
Beclometasone
dipropionate 50 mcg

Qvar® 100

Autohaler® Inhaler
CFC-free

Each actuation delivers:
Beclometasone
dipropionate 100 mcg

For the list of inactive ingredients in this preparation, see section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet includes concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not intended for use in children below the age of 5.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Qvar inhaler is intended for the prevention and treatment of asthma in adults and children above the age of 5.

Therapeutic Group:

Inhaled corticosteroids

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

- ☒ There is a known sensitivity to beclometasone or to any of the other ingredients of this medicine.
- ☒ You are suffering, or have suffered in the past, from pulmonary tuberculosis or herpes.
- ☒ Qvar is not intended for relief during an acute asthma attack which does not respond to treatment with bronchodilators and corticosteroids. If you are suffering from a sudden asthma attack, Qvar cannot help; use a quick-acting "reliever" inhaler for this purpose and carry it with you at all times.

Special warnings regarding use of Qvar

Before treatment with Qvar, notify the doctor if:

If it seems to you that your asthma is getting worse, if you suffer from shortness of breath and wheezing more than usual, if it seems to you that the medicine is less effective or that your condition is not improving, or if you have to use larger quantities of the medicine; the doctor may increase the dosage of your steroids (tablets or inhaler) or change the treatment. If you have a respiratory tract infection, the doctor may also prescribe a course of antibiotics. Do not drink alcohol during the course of treatment.

The doctor may prescribe this medicine to replace steroid tablets, and then you will use both medicines concomitantly for a short time. It is important to follow the doctor's instructions. Whilst reducing the steroid dosage, you may not feel well even if you breathe well. If you suffer from additional allergies, discontinuation of the steroids may cause exacerbation of the symptoms. If this happens, keep using the medicine and refer to the doctor.

If you have been treated for a long time with a high dosage of inhaled steroids, you may require steroid tablets or injections under conditions such as: hospitalization after a serious accident, before an operation, during a severe asthma attack, if you also have an inflammation of the respiratory tract or another serious ailment. The doctor will decide if you need additional steroid treatment, for how long and how to reduce the dosage when you feel better. If you have to go to the hospital, take the medicine with you.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or the pharmacist if you are taking:

- disulfiram
- metronidazole

Pregnancy and Breastfeeding

If you are pregnant, planning to become pregnant, or are breastfeeding, consult the doctor before taking this medicine.

Use in children

This medicine is not intended for use in children below the age of 5.

Driving

Qvar should not affect your ability to drive or operate machines.

3. HOW SHOULD YOU USE THIS MEDICINE?

Always use this medicine according to the doctor's instructions. If you are unsure, check with the doctor or pharmacist.

The dosage and treatment regimen will be determined by the doctor only.

Qvar is available in two strengths and the doctor will determine the strength which best suits your condition.

The usual dosage is generally:

Qvar 50 inhaler

Adults (including the elderly) and children above the age of 12:

Mild Asthma

Starting dose: one puff, twice a day (i.e. a total of 100 micrograms/day). This can be increased to up to two puffs, twice a day (i.e. a total of 200 micrograms/day).

Moderate Asthma

Starting dose: two puffs, twice a day (i.e. a total of 200 micrograms/day). This can be increased to up to 4 puffs, twice a day (i.e. a total of 400 micrograms/day).

Severe Asthma

Starting dose: 4 puffs, twice a day (i.e. a total of 400 micrograms/day). This can be increased to up to 8 puffs, twice a day (i.e. a total of 800 micrograms/day). The maximum daily dosage is a total of 16 puffs (i.e. 800 micrograms/day).

Qvar 100 inhaler

Adults (including the elderly) and children above the age of 12:

Mild Asthma

Starting dose: one puff a day (i.e. a total of 100 micrograms/day). This can be increased to up to one puff, twice a day (i.e. a total of 200 micrograms/day).

Moderate Asthma

Starting dose: one puff, twice a day (i.e. a total of 200 micrograms/day). This can be increased to up to two puffs, twice a day (i.e. a total of 400 micrograms/day).

Severe Asthma

Starting dose: 2 puffs, twice a day (i.e. a total of 400 micrograms/day). This can be increased to up to 4 puffs, twice a day (i.e. a total of 800 micrograms/day). The maximum daily dosage is total of 8 puffs (i.e. 800 micrograms/day).

Children from 5 years of age and up

Mild persistent or moderate asthma: 50 micrograms, twice a day.

In severe cases: 100 micrograms, twice a day.

The maximum daily dosage for children is 100 micrograms, twice a day.

Do not exceed the recommended dose.

If you accidentally took an overdose of the medicine, or if a child accidentally inhaled this medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or the pharmacist.

Be sure to get a new prescription before the current inhaler is emptied.

How can you contribute to the success of the treatment?

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

4. SIDE EFFECTS

As with any medicine, use of Qvar may cause side effects among some users. Do not be alarmed when reading the list of side effects; you may not suffer from any of them.

If after using this medicine you feel wheezing or tightness in the chest, stop using the medicine and refer to the doctor immediately.

Stop use of the medicine and refer to a doctor immediately if:

an allergic reaction develops, manifested by swelling of the lips, face or neck (leading to breathing difficulties), skin rash (hives). This is a rare reaction but can be life-threatening.

Use of the medicine may cause problems in the production of corticosteroids in the body. Continue using the medicine and refer to the doctor immediately if you suffer from abdominal pain, weakness, vomiting. This is especially important if you suffer from another ailment, if you are due to undergo surgery, or if you suffer from any infection.

Additional side effects:

Hoarseness, pain in the mouth or oral thrush (can be prevented by rinsing your mouth after using the inhaler), nausea, headache, dizziness or feeling faint, tremor, changes in taste, increase in wheezing, shortness of breath, cough.

Problems sleeping, depression, anxiety, restlessness, nervousness, over-excitedness (these effects are more common in children).

At high dosages, and in prolonged treatment, the following side effects have been reported:

Bone thinning, clouding of the lens of the eye (cataract) - leads to blurred vision, loss of vision due to acute increase in intraocular pressure.

Children and adolescents who use the medicine for a long period may suffer from retarded growth. The doctor may monitor your child's height.

If any of these side effects worsens, or if you experience a side effect not mentioned in this leaflet, consult the doctor.

5. HOW TO STORE THIS MEDICINE

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use this medicine after the expiry date (Expiry date) indicated on the package. The expiry date refers to the last day of that month.

Do not store at a temperature exceeding 25°C.

Avoid exposure to direct sunlight or heat.

Do not freeze.

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

Medicines should not be disposed of via wastewater or household waste. If the doctor decides to stop treatment, return the canister to the doctor or pharmacist for safe disposal. These measures help to protect the environment.

6. FURTHER INFORMATION

Aside from the active ingredient, this medicine also contains:

Propellant HFA-134a (Norflurane), ethanol

What does the medicine look like and what are the contents of the package

Qvar inhaler is a pressurised canister closed with a metering valve.

The inhaler contains 200 doses.

License holder

Salomon, Levin & Elstein Ltd.,
P.O.B. 3696, Petah-Tikva.

Distributor

Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190, Petah-Tikva.

Manufacturer and address

3M Health Care Ltd., UK.

This leaflet was checked and approved by the Ministry of Health in February 2013.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Qvar 50: 139.28.30660.00

Qvar 100: 139.29.30661.00

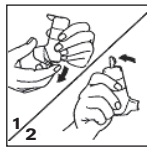
QVAR AUT PL SH 200313

Qvar® Instructions for use

Before Use

If this is a new device or if it has not been in use for a period of 2 weeks or more, test it before use by releasing 2 puffs into the air as follows:

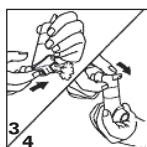
- 1 - Remove the protective cover from the mouthpiece by pulling down on the lip at the back of the product (Fig. 1).
- 2 - Point the mouthpiece away from you, so that the medicine will be released into the air after pressing. Push the lever up, and leave it in that position (Fig. 2).



- 3 - Now, to release a dose, push the dose release slide on the bottom of the device in the direction indicated by the arrow (Fig. 3).

- 4 - To release the second dose, return the lever to its down position (Fig. 4) and repeat steps 2 and 3.

After releasing the second dose, return the lever to its down position; now the device is ready to release a dose of the medicine.

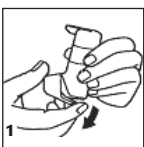


Do not use the dose release slide to take the medicine. The Autohaler device will automatically release a dose when you begin to breathe in through the mouthpiece.

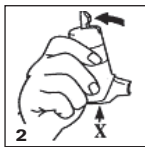
Instructions for use are detailed below:

How to Use the Qvar Autohaler

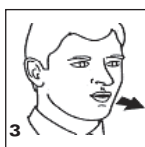
- 1 - Remove the protective cover from the mouthpiece by pulling down on the lip at the back of the product (Fig. 1).



- 2 - Hold your Autohaler device upright as shown. Push the lever up and leave it in that position. Continue to hold your device upright, while ensuring that your hand is not blocking the air vent (marked by an X in Fig. 2) at the bottom of the device.



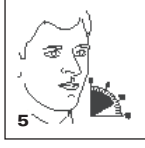
- 3 - Exhale as much as you can, immediately place the mouthpiece in your mouth and close your lips around it (Fig. 3).



- 4 - Inhale slowly and deeply through the mouthpiece. Do not stop inhaling, even when you hear the slight click and feel the dose of medicine in your mouth, as it is important that you carry on inhaling even after the dose is released.



- 5 - Hold your breath for 10 seconds and exhale slowly.



- 6 - Lower the lever to the down position after each puff. If your doctor has instructed you to use more than one dose, repeat steps 2-6. After use, replace the cover on the mouthpiece.

How to tell if your Qvar Device is empty

When the device has emptied - you will not feel or hear the medicine being discharged.

Instructions for cleaning the device

In order to preserve hygiene, the mouthpiece of the Autohaler should be cleaned once a week with a clean dry tissue or cloth. **Do not wash or store any part of the device in water.**

Warning!

Do not insert a drying cloth or anything else into the Autohaler device since it may cause damage to the operating parts of the device.

Do not take the device apart.

If you have any further questions regarding use of this product, refer to the doctor or pharmacist.