

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

This medicine is dispensed with a doctor's prescription only

Qvar Autohaler 50 inhaler Qvar Autohaler 100 inhaler

Composition

Qvar 50

Each metered puff contains:
Beclometasone dipropionate 50 mcg

Qvar 100

Each metered puff contains:
Beclometasone dipropionate 100 mcg

Inactive ingredients and allergens: see section 2, 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

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

This medicine is not intended for use in children aged under 5 years.

1. What is this medicine intended for?

Qvar Autohaler is used to prevent and treat asthma in adults and in children over 5 years old.

Therapeutic group:

inhaled corticosteroids.

Qvar Autohaler works in your lungs to make breathing easier by reducing inflammation, swelling, and irritation in the airways. This type of medicine is used for prevention, so it needs to be taken regularly every day even if you have no symptoms.

This inhaler will not give immediate relief of wheezing or breathlessness during a sudden asthma attack. In such cases you will need to use a quick-acting 'reliever' inhaler in addition to Qvar Autohaler.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient (beclometasone) or to any of the other ingredients in this medicine
- you are sensitive (allergic) to other inhalers
- you are suffering from sudden breathlessness. This inhaler will not help. Use a quick-acting 'reliever' inhaler for this purpose and carry it with you at all times.

Special warnings about using Qvar

Talk to your doctor before treatment with Qvar if:

- you have tuberculosis now or have had it in the past
- you are sensitive (allergic) to other inhalers
- you need to avoid drinking alcohol for any reason
- your asthma seems to be getting worse. If you are more short of breath and wheezy than usual, if your quick-acting reliever inhaler seems to be less effective or you need to use it more than usual, or you are not getting better. Your doctor may increase the dose of your steroid inhaler or give you a temporary course of steroid tablets, or change your treatment altogether. If you have an infection in your airways, your doctor may also prescribe a course of antibiotics.
- when transferring from steroid tablets to inhaled steroids, you feel generally unwell, develop a rash, eczema or a runny nose and sneezing, even though you get relief in your airways. Do not stop treatment with your inhaler unless your doctor tells you to.

Important points to remember while you are using this medicine:

- Your doctor may prescribe this medicine to replace steroid tablets, in which case you will have to use both medicines together for a short time. It is important to follow your doctor's instructions. While you are reducing the dose of steroid tablets, you may feel generally unwell even though you can breathe as well as normal or better. If you have other allergies, you may find that stopping your steroid tablets makes the symptoms worse. If this happens, keep using your inhaler and consult your doctor.
- If you have been treated for a long time with high doses of inhaled steroids, you may require steroids in tablets or by injection in times of stress. For example, during admission to hospital after a serious accident, before surgery, during an acute attack of asthma, or if you have an inflammation in your airways or other serious illness. Your doctor will decide if you need extra steroid treatment, how long you need to take it, and how to reduce the dose when you get better.
- There may be times when you need to take steroids in tablets as well as using your inhaler, for example if you have worsening asthma attacks, an inflammation of your airways, or before surgery. Your doctor may prescribe a small amount of steroid tablets for these situations and will explain how to take them. Contact your doctor immediately if you think that you need to take steroid tablets, even if you have some tablets at home.
- Visit your doctor regularly for a review of your condition.
- If you have to go into hospital, remember to take this and your other medicines including those bought without prescription with you.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

This medicine is not intended for use in children under 5 years old.

Other medicines and Qvar Autohaler

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Disulfiram
- Metronidazole

- Certain medicines may increase the effects of Qvar Autohaler and your doctor may wish to monitor you more carefully if you are taking these medicines (including some medicines for AIDS [HIV] that contain ritonavir or cobicistat).

Pregnancy, breastfeeding, and fertility

If you are pregnant, considering pregnancy, or are breastfeeding, ask your doctor for advice before taking this medicine.

Driving and using machines

Qvar is not known to affect your ability to drive or operate machines.

Important information about some of this medicine's ingredients

This medicine contains 4.7 mg of alcohol (ethanol) in each metered dose. This is equivalent to less than 1 ml of beer or wine.

The small amount of alcohol in this medicine will not have a noticeable effect.

Tell your doctor if you need to avoid drinking alcohol for any reason

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

This inhaler has a softer feel and a different taste than other inhalers you may have used before. This inhaler contains an extra fine aerosol, which results in more of each dose being delivered to your lungs. Therefore, your doctor may prescribe a lower dose of this inhaler than your previously used inhaler.

Even when your doctor has prescribed a lower dose inhaler, you may find that the number of puffs you are asked to take is the same as from your previous inhaler. This is because this inhaler may have a lower strength (this means that each puff of this inhaler contains less beclometasone dipropionate than your previous inhaler).

Only your doctor will determine your dose and how you should take this medicine.

Do not take more puffs than your doctor has told you to. In some circumstances, your doctor may prescribe a greater number of puffs.

The recommended dosage is usually:

Qvar 50 Autohaler

Adults (including the elderly) and children over 12 years old:

• Mild Asthma

Starting dose: one puff twice a day (which is a total of 100 mcg a day). This may be increased up to 2 puffs twice a day (which is a total of 200 mcg a day).

• Moderate Asthma

Starting dose: 2 puffs twice a day (which is a total of 200 mcg a day). This may be increased up to 4 puffs twice a day (which is a total of 400 mcg a day).

• Severe Asthma

Starting dose: 4 puffs twice a day (which is a total of 400 mcg a day). This may be increased up to 8 puffs twice a day (which is a total of 800 mcg a day).

The maximum daily dose is a total of 16 puffs (which is 800 mcg a day).

Qvar 100 Autohaler

Adults (including the elderly) and children over 12 years old:

• Mild Asthma

Starting dose: one puff a day (which is a total of 100 mcg a day). This may be increased up to one puff twice a day (which is a total of 200 mcg a day).

• Moderate Asthma

Starting dose: one puff twice a day (which is a total of 200 mcg a day). This may be increased up to 2 puffs twice a day (which is a total of 400 mcg a day).

• Severe Asthma

Starting dose: 2 puffs twice a day (which is a total of 400 mcg a day). This may be increased up to 4 puffs twice a day (which is a total of 800 mcg a day).

The maximum daily dose is a total of 8 puffs (which is 800 mcg a day).

Children aged 5 years and over

Consistently mild asthma or moderate asthma: 50 mcg twice a day.

In severe cases: 100 mcg twice a day.

The maximum daily dose for children is 100 mcg twice a day.

Do not exceed the recommended dose.

What to do if you think your treatment is not working:

If you think your usual treatment is not working, for example: your symptoms are not getting better or they are getting worse, or you need to use more puffs from your quick-acting 'reliever' inhaler, or if your quick-acting 'reliever' inhaler does not seem to be working as well as before, or your peak flow falls, tell your doctor because your asthma may be getting worse.

If you have accidentally taken an overdose, or if a child has accidentally inhaled some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take your prescribed dose as soon as you remember unless it is almost time for the next dose. **Do not take a double dose** to make up for a forgotten dose. Then continue to use this medicine at the regular times, as prescribed by your doctor. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Make sure to get a new prescription before this inhaler is empty.

If you stop taking this medicine

This inhaler must be used regularly, even when you feel well.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

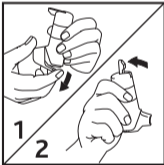
Directions for use

Before use

If this is a new inhaler or if you have not used it for two weeks or more, it must be tested before use by releasing 2 puffs into the air in the following way:

1. Take the cover off the mouthpiece by pulling down on the lip at the back of the inhaler (Fig 1).
2. Point the mouthpiece away from you so that the medicine will go into the air when you press.

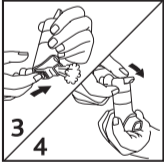
Push the lever up so that it stays up (Fig. 2).



3. Then, 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 you need to return the lever to its previous down position (Fig. 4) and repeat steps 2 and 3.

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

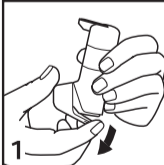


How to use Qvar Autohaler

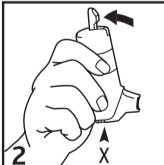
Do not use the dose release slide to take your medicine; the Autohaler device will automatically release a dose when you begin to breathe in from the mouthpiece.

Directions for use are listed below:

1. Take the cover off the mouthpiece by pulling down on the lip at the back of the inhaler (Fig. 1).



2. Hold your Autohaler device upright as shown. Push the lever up so that it stays up. Continue to hold your device upright, making sure that your hand is not blocking the air vent (marked by X in Fig. 2) at the bottom of the device.



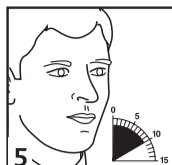
3. Breathe out as far as is comfortable, then immediately place the mouthpiece in your mouth and close your lips around it (Fig. 3).



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



5. Hold your breath for 10 seconds and then breathe out slowly.



6. The lever must be lowered to the down position after each puff. If your doctor has prescribed more than one puff, repeat steps 2 to 6. After use, replace the cover on the mouthpiece.

Rinse your mouth after using your inhaler.

How to tell when your Qvar Autohaler is empty

When the device is completely empty you will not feel or hear the medicine being released.

Instructions for cleaning your device

For normal hygiene, the mouthpiece of your Autohaler should be cleaned once a week with a clean, dry cloth or tissue. Rinse your mouth with water after using your inhaler.

Warning:

- Do not wash or put any part of your inhaler in water.
- Do not push a drying cloth or anything else into any part of the Autohaler device since this may cause damage to the device's operating parts.
- Do not take the device apart.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side effects

Like with all medicines, using Qvar may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

If immediately after taking this medicine, you feel wheezy or tight-chested stop using this medicine. Use your reliever inhaler to help your breathing and contact your doctor immediately.

Stop using this medicine and contact your doctor immediately or go to hospital if:

- you develop an allergic reaction (swelling of the lips, face or neck [leading to difficulty in breathing], skin rash or hives).

This is a very serious but very rare side effect. You may need urgent medical attention or hospitalization.

Treatment with this medicine may affect the normal production of corticosteroids in the body. Your doctor may order blood tests from time to time to check for this condition.

Keep using your inhaler but see your doctor immediately if you feel unwell, particularly with any of the following conditions:

- abdominal pain
- weakness
- vomiting

This is especially important if you have been exposed to other stress such as another illness, surgery, or infection.

The following side effects may also occur in patients taking this medicine. If you experience any of these effects, **keep using your medicine but see your doctor** if they last for a while or they are worrying you:

Common side effects—may affect 1-10 in 100 users

- hoarseness
- difficulty in swallowing accompanied by earache and swollen glands, sore throat (pharyngitis)
- sore mouth or thrush (white spots in your mouth and throat). These are less likely if you rinse your mouth out with water after using your inhaler. If you get thrush, your doctor may prescribe a medicine.
- changes in taste.

Uncommon side effects—may affect 1-10 in 1,000 users

- nausea
- headache
- tremor
- feeling dizzy or faint
- difficulty in breathing, increase in wheezing, shortness of breath, cough (bronchospasm)
- blurred vision.

Very rare side effects—may affect less than 1 in 10,000 users

- bone thinning
- clouding of the lens of the eye (cataract) resulting in blurred vision
- loss of vision due to abnormally high pressure in the eye.

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- sleeping problems, depression or feeling worried, restlessness, nervousness, being over-excited or irritable. These effects are more common in children.

Children and adolescents who use the inhaler for a prolonged period may grow more slowly. Your doctor may monitor the height of your child.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Do not store above 25°C.

Avoid exposure to direct light or heat.

Do not freeze.

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

Do not throw away medicines via wastewater or household waste. If your doctor decides to stop treatment, return the canister to your doctor or pharmacist for safe disposal. These measures help to protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Norflurane (propellant 134A), ethanol.

What the medicine looks like and contents of the pack

The Qvar Autohaler is an aluminium canister closed with a filter and metering valve. It contains a colourless solution. The inhaler supplies 200 doses.

Registration holder's name and address

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

Manufacturer's name and address

Kindeva Drug Delivery Limited, Derby Road, Loughborough, Leicestershire U.K.

This leaflet was revised in November 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Qvar 50: 139.28.30660

Qvar 100: 139.29.30661