

Package leaflet: Information for the user

Qvar® Easi-Breathe® 50 micrograms per actuation Inhaler
Qvar® Easi-Breathe® 100 micrograms per actuation Inhaler

Beclometasone Dipropionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Qvar Easi-Breathe Inhaler is and what it is used for
2. What you need to know before you use Qvar Easi-Breathe Inhaler
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1. What Qvar Easi-Breathe Inhaler is and what it is used for

Qvar Easi-Breathe Inhaler contains beclometasone dipropionate, which belongs to a group of medicines known as corticosteroids.

Qvar Easi-Breathe Inhaler is used to prevent the symptoms of mild, moderate, or severe asthma in patients who require regular treatment.

How your medicine works

- Qvar Easi-Breathe Inhaler works deep in your lungs to make breathing easier by reducing the inflammation, swelling, and irritation in the airways. This type of medicine is known as a 'preventer'. 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. You will need to use a 'reliever' inhaler, which contains a different medicine. You should still continue to use this inhaler.
- you are suffering from a sudden attack of breathlessness. It will not help. Use a quick-acting 'reliever' inhaler for this purpose and carry it with you at all times

2. What you need to know before you use Qvar Easi-Breathe Inhaler

Do not use Qvar Easi-Breathe Inhaler if you:

- are allergic (hypersensitive) to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6)
- are allergic to other similar inhalers.

Warnings and precautions

Talk to your doctor before taking this medicine if:

- you are suffering from tuberculosis (TB) now or have suffered from it in the past.

- you must avoid alcohol for any reason.
- your asthma seems to be getting worse. Perhaps you are more wheezy and short of breath than usual, your 'reliever' inhaler seems to be less effective, you require more puffs from your 'reliever' inhaler than usual, or you do not seem to be getting better. Your doctor may need to increase the dose of your steroid inhaler or give you a course of steroid tablets, or change your treatment altogether. If you have an infection in your chest your doctor may prescribe a course of antibiotics.
- when transferring from steroid tablets to an inhaler you find that, even if your chest is getting better, you feel generally unwell, you develop a rash, eczema or a runny nose and sneezing (rhinitis). 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 inhaler to replace steroid tablets, which may mean for a short time you have to take both medicines. It is important to follow your doctor's advice. Whilst you are reducing the number of steroid tablets that you take 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 them worse. If this happens, keep using your inhaler and tell your doctor.
- If you have been treated for a long time with high doses of inhaled steroid, you may require a course of steroid tablets or possibly a steroid injection in times of stress. For example, during admission to hospital after a serious accident, before an operation, during an acute attack of asthma or if you have a chest infection or other serious illness. Your doctor will decide if you need any extra steroid treatment and will also advise you as to how long you need to take the course of steroid tablets and how you should reduce these as you get better.
- There may be times when you need to take steroid tablets as well as using your inhaler, for example if you have worsening asthma attacks, you get a chest infection, or you need an operation. Your doctor may give you a small supply of steroid tablets to be taken in these situations; if he does, you will be given full instructions on how and when to take them. Contact your doctor immediately if you think that you need to take steroid tablets, even if you have your own supply.
- You should have been given a steroid card with this inhaler, if you have not, please ask your pharmacist for one. Make sure you carry your steroid card with you at all times until your doctor decides that it is no longer necessary.
- Visit your doctor regularly for a review of your condition.
- If you have to go into hospital, remember to take all your inhalers and other medicines with you.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Qvar Easi-Breathe Inhaler

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are taking:

- Disulfiram
- Metronidazole

Some medicines may increase the effects of QVAR Easi-breathe and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy, breast-feeding and fertility

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking this medicine.

Driving and using machines

Qvar Easi-Breathe Inhaler is not known to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Qvar:

Qvar contains a small amount of alcohol.

3. How to use Qvar Easi-Breathe Inhaler

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

There are two strengths of the Qvar Easi-Breathe device available and your doctor will have chosen 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 is an extra fine aerosol which results in more of each dose being delivered to your lungs. Your doctor may, therefore, prescribe a lower dose of this inhaler than your previously used inhaler.

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

Do not take more puffs than your doctor has told you to. In some circumstances, your doctor may prescribe more than the usual number of puffs. You should check with your doctor or pharmacist if you are not sure. The usual number of puffs to take is as follows:

Qvar Easi-Breathe 50 micrograms Inhaler

Adults (including the elderly) and children over 12 years

- **Mild Asthma**
The starting dose is one puff twice a day. This may be increased up to two puffs twice a day.
- **Moderate Asthma**
The starting dose is two puffs twice a day. This may be increased up to four puffs twice a day.
- **Severe Asthma**
The starting dose is four puffs twice a day. This may be increased up to eight puffs twice a day.

The maximum dose is a total of sixteen puffs a day.

Qvar Easi-Breathe 100 micrograms Inhaler

Adults (including the elderly) and children over 12 years

- **Mild Asthma**
The Qvar 100 Easi-Breathe device is not suitable for the starting dose. It is suitable for an increased dose of one puff twice a day.
- **Moderate Asthma**
The starting dose is one puff twice a day. This may be increased to two puffs twice a day.
- **Severe Asthma**
The starting dose is two puffs twice a day. This may be increased up to four puffs twice a day.

The maximum dose is a total of eight puffs a day.

Use in children under 12 years

Qvar Easi-Breathe Inhaler is not recommended for use in children under 12 years.

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 are getting worse, or you need to use more puffs from your reliever inhaler, or if your reliever inhaler does not

seem to be working as well as usual, or your peak flow falls, please tell your doctor. Your asthma may be getting worse.

If you use more Qvar Easi-Breathe Inhaler than you should

It is important that you take your dose as stated on the pharmacist's label, or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you accidentally take more puffs than recommended, please tell your doctor immediately.

If you forget to use Qvar Easi-Breathe Inhaler

If you forget to use this inhaler at your usual time, take your recommended number of puffs as soon as you remember unless it is nearly time to use your inhaler again. **DO NOT** take a double dose to make up for a forgotten dose. Then continue to use your inhaler regularly at the correct time, as prescribed by your doctor.

If you stop using Qvar Easi-Breathe Inhaler

This inhaler must be used regularly, even when you feel well. You must not stop using your inhaler unless your doctor tells you to.

Ask your doctor for a prescription for a replacement inhaler before this one is empty.

If your doctor decides to stop treatment, return the inhaler to your doctor or pharmacist for safe disposal.

Using your Qvar Easi-Breathe Inhaler

Qvar Easi-Breathe CFC-Free Inhaler is designed to make it easier for you to use.

It is a breath-operated inhaler. This means it only releases a dose when you breathe in.

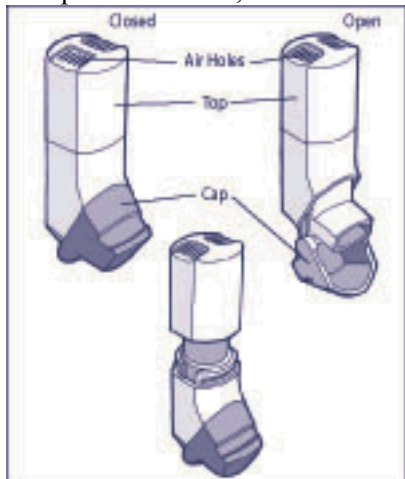
Before Use

Before using your inhaler, please read this leaflet carefully and follow the instructions.

- Test spray the inhaler by firing two shots into the air before you use it for the first time, or if you have not used it for a period of two weeks or more.
- To test spray your inhaler, unscrew the top of it so you can see the metal can inside. Open the cap and spray the aerosol by pressing the can with your finger or thumb. Close the cap and put the top back on.

Opening

To open the inhaler, fold down the cap which fits over the mouthpiece.



1. Hold the inhaler upright and open it by folding down the cap which fits over the mouthpiece.



2. Breathe out normally as far as you comfortably can. Then hold the mouthpiece firmly between your lips. Hold the inhaler upright and make sure that your hand is not blocking the air holes. Breathe in slowly and deeply through the mouthpiece. Don't stop breathing when the inhaler puffs the dose into your mouth. Carry on until you have taken a deep breath.



3. Take the inhaler out of your mouth and hold your breath for 10 seconds or as long as you comfortably can. Then breathe out slowly.



4. After you have used your inhaler, hold it upright and close the cap immediately.
5. If you need to take more than one puff, close the cap, wait about one minute and then start again from step 1.

How to tell when your Qvar Easi-Breathe Inhaler is empty

When the canister is completely empty you will not feel or hear any propellant being discharged.

Cleaning instructions

For normal hygiene, the mouthpiece of your inhaler should be cleaned weekly with a clean, dry tissue or cloth. You should also rinse your mouth with water after using your inhaler.

Do not wash or put any part of your inhaler in water.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If immediately after taking a puff of this inhaler you feel wheezy or tight chested do not take any more puffs. Use your reliever inhaler to help your breathing and contact your doctor immediately.

If the following happens, stop using your inhaler and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

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

Treatment with Qvar Easi-Breathe inhalers may affect the normal production of corticosteroids in the body. If you become unwell, particularly with any of the following you should see your doctor:

- abdominal pain
- weakness
- vomiting.

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

In addition, the following side effects have been reported for high doses, taken for prolonged periods:

- 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.

The following side effects have been reported in patients taking beclometasone dipropionate:

- hoarseness
- difficulty in swallowing accompanied by earache and swollen glands, sore throat (pharyngitis)
- a sore mouth or thrush (white spots in mouth and throat). These are less likely if you rinse your mouth out with water after using your inhaler. If you get thrush, talk to your doctor who may recommend a medicine to treat you
- feeling sick
- headache
- feeling dizzy or faint
- tremor
- change in taste
- difficulty in breathing, increase in wheezing, shortness of breath and cough (bronchospasm)
- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children (Frequency not known).
- Blurred vision (uncommon (may affect up to 1 in 100 people))

Children or adolescents who are using the inhaler for a prolonged period may grow more slowly. Your doctor may therefore wish to monitor the height of a child receiving prolonged treatment with Qvar Easi-Breathe inhalers.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Qvar Easi-Breathe Inhaler

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Avoid storage in direct sunlight or heat. You can use your inhaler at temperatures as low as -10°C. However, protect from frost.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

Do not use Qvar Easi-Breathe Inhaler after the expiry date that is stated on the outer packaging after EXP. The expiry date refers to the last day of that month.

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

6. Contents of pack and other information

Your Qvar Easi-Breathe aerosol does not contain CFCs, instead the inhaler contains a hydrofluoroalkane (called propellant HFA-134a or norflurane) as an inactive ingredient. Hydrofluoroalkanes have been developed as a replacement for CFCs.

What Qvar Easi-Breathe Inhaler contains:

- The active ingredient is beclometasone dipropionate.
The Qvar Easi-Breathe 50 micrograms Inhaler contains 50 micrograms of beclometasone dipropionate per puff.
The Qvar Easi-Breathe 100 micrograms Inhaler contains 100 micrograms of beclometasone dipropionate per puff.
- The other ingredients are propellant HFA-134a (norflurane) and ethanol anhydrous.

What Qvar Easi-Breathe Inhaler looks like and contents of the pack:

- Qvar Easi-Breathe is a pressurised inhalation solution
- Your inhaler contains 100 or 200 puffs.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Qvar Easi-Breathe Inhalers are made by IVAX Pharmaceuticals Ireland, Waterford, Ireland. The marketing authorisation holder is Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, UK.

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For further information about asthma, contact Asthma UK, the independent UK charity working to conquer asthma:
Asthma UK, Summit House, 70 Wilson Street, London, EC2A 2DB
Asthma Helpline: 0845 7 010203
(Open Monday to Friday, 9am to 5pm).