

PACKAGE LEAFLET: INFORMATION FOR THE USER

QVAR AUTOHALER 50 & 100 micrograms PRESSURISED INHALATION, SOLUTION 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 Autohaler is and what it is used for
2. What you need to know before you use Qvar Autohaler
3. How to use Qvar Autohaler
4. Possible side effects
5. How to store Qvar Autohaler
6. Contents of the pack and other information

1. What Qvar Autohaler is and what it is used for

Qvar Autohaler contains the active substance beclometasone dipropionate, which is one of a group of medicines known as corticosteroids.

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

This medicine is indicated in adults and children aged 5 years and older (see section 3, “How to use Qvar Autohaler”).

How your medicine works

- Qvar Autohaler 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.

2. What you need to know before you use Qvar Autohaler

DO NOT use Qvar Autohaler if you:

- are allergic (hypersensitive) to beclometasone dipropionate or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor before you start to use this medicine if you:

- are currently suffering from tuberculosis (TB) or have suffered from it in the past
- are due to have or have recently had surgery
- are currently using topical corticosteroids (i.e. creams).

Prolonged treatment with high doses of inhaled corticosteroids, such as Qvar Autohaler, may make your

adrenal glands work less efficiently and is more likely to cause side effects (see section 4, “Possible side effects”).

If you experience intense wheezing and breathing problems immediately after using Qvar Autohaler, you might need **urgent** medical attention (see section 4, “Possible side effects”).

Switching from steroid tablets to Qvar Autohaler

- Your doctor may prescribe this inhaler to replace steroid tablets, which may mean that 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.
- 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 they do, 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.
- Your doctor will monitor you and review your condition regularly.
- If you have to go into hospital, remember to take all your inhalers and other medicines with you.

Other medicines and Qvar Autohaler

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

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

- disulfiram (used to treat chronic alcoholism)
- metronidazole, an antibiotic (used to treat infections)
- topical corticosteroids (used to treat rash, eczema, dermatitis).

Children and adolescents

Qvar Autohaler is indicated for children aged 5 years and over (see section 3, “How to use Qvar Autohaler”).

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 Autohaler.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking this medicine; your doctor will determine if the expected benefit of using this medicine is greater than any potential risk to the baby.

Qvar Autohaler contains ethanol (alcohol)

Qvar Autohaler contains a small amount of ethanol (alcohol), less than 100 mg per dose.

3. How to use Qvar Autohaler

There are two strengths of the Qvar Autohaler available and your doctor will have chosen the strength which best suits your condition.

Remember that it is important to take your medicine as your doctor has told you. The label should remind you how many puffs to take and how often.

Qvar Autohaler has a softer feel and a different taste than inhalers you may have used before, because it is an extra fine aerosol, which results in more of each dose being delivered to your lungs. Your doctor may prescribe a lower dose of this inhaler than your previous beclometasone dipropionate inhaler.

Qvar is for oral inhalation use only.

This inhaler **MUST be used regularly**, even when you feel well. You **MUST NOT** stop using your inhaler unless your doctor tells you to (see “If you stop using Qvar Autohaler”).

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.

An adult should always supervise children when they use Qvar Inhaler. Children may need help to use their inhaler. Parents can help by spraying the aerosol when the child begins to breathe in.

The usual number of puffs to take is:

Qvar 50 Autohaler

Adults (including the elderly)

- **Mild to moderate asthma:**
The starting dose ranges from **one to four puffs twice a day**. This may be increased up to eight puffs twice a day.
- **Severe asthma:**
Up to eight puffs twice a day.
- The maximum dose is a total of sixteen puffs a day.

Children aged 5 years and over

- The dose for children is **one puff twice a day**. Your doctor may increase this to two puffs twice a day when symptoms are not adequately controlled.
- When control of symptoms has been established, the dose should be reduced to the lowest dose required to maintain control of symptoms.
- The maximum dose for children is a total of four puffs a day.

Qvar 100 Autohaler

Adults (including the elderly)

- **Mild to moderate asthma:**
The starting dose is **one or two puffs twice a day**. This may be increased to four 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.

Children aged 5 years and over

- Your doctor may prescribe Qvar 100 for children whose symptoms are not adequately controlled using Qvar 50.
- The dose for children is **one puff twice a day**.
- When control has been established, the dose should be reduced to the lowest dose required to maintain control of symptoms. This can be done using Qvar 50.
- The maximum dose is a total of two puffs a day.

Using your Qvar Autohaler Device

Before using your inhaler, please read this leaflet carefully and follow the instructions. If you are not sure how to use the inhaler device, ask your doctor or a pharmacist.

Qvar Autohaler 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.

You **MUST** clean the mouthpiece of your inhaler **once a week** with a clean dry tissue or cloth to prevent blockage. **DO NOT** wash or put any part of the inhaler in water.

Before use

If this is a new device or if you have not used it for **2 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 from the mouthpiece, by pulling down on the lip at the back (fig. 1).
2. Point the mouthpiece away from you so that the puffs of medicine will go into the air. Push the lever up so that it stays up (fig. 2).
3. Then, to release a puff, push the dose release slide on the bottom of the device in the direction indicated by the arrow on it (fig. 3).
4. To release the second puff you need to return the lever to its down position (fig. 4) and follow steps 2 and 3 again. After releasing the second puff, return the lever to its down position, to be ready to take a puff of your medicine.

How to use your Qvar Autohaler device

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.

The instructions for taking a puff are given below.

1. Take the cover off from the mouthpiece, by pulling down on the lip at the back.
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.
4. Breathe in slowly and deeply through the mouthpiece. **DO NOT** stop breathing in when you hear the slight click and feel the puff in your mouth, as it is important that you carry on breathing in after the puff 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 - 6. After use, replace the cover on the mouthpiece.
7. If possible, rinse your mouth with water after using the Autohaler device.

How to tell when your Qvar Autohaler device is empty

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

Cleaning your Qvar Autohaler device

For normal hygiene, the mouthpiece of your Autohaler device should be cleaned **weekly** with a clean, dry tissue or cloth.

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 it may cause damage to its operating parts.
DO NOT take the Autohaler device apart.

What to do if you think your treatment is not working

Please tell your doctor if you think your usual treatment is not working, for example:

- your symptoms are not getting better
- your symptoms are getting worse
- you need to use more puffs from your reliever inhaler
- your reliever inhaler does not seem to be working as well as usual
- your peak flow falls.

Any of these could be a sign of your asthma getting worse.

If you use more of your Qvar Autohaler 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/a child accidentally take(s) more puffs than recommended, please contact your/their doctor.

If you forget to use Qvar Autohaler

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 Autohaler

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.

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

4. Possible side effects

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

If you experience wheezing or tightness in your chest immediately after taking a puff of this medicine, DO NOT take any more puffs. Use your 'reliever' inhaler to help your breathing and contact your doctor IMMEDIATELY.

STOP using your inhaler and tell your doctor IMMEDIATELY or go to the casualty department at your nearest hospital if the following happens:

- 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.

The following side effects have also been reported:

Very common side effects affecting more than 1 in 10 users:

- thrush (white spots in your mouth and throat).

Common side effects affecting more than 1 in 100 users, but less than 1 in 10 users:

- hoarseness
- sore throat.

These are less likely if you rinse your mouth out with water after using your inhaler. If you get thrush, your doctor may recommend a medicine to treat you.

Uncommon side effects affecting more than 1 in 1,000 users, but less than 1 in 100 users:

- rash, nettle rash or itching.

Rare side effects affecting more than 1 in 10,000 users but less than 1 in 1,000 users:

- nausea (feeling sick).

Very rare side effects affecting less than 1 in 10,000 users:

- condition of the adrenal glands causing weight gain, rounded (moon-shaped) face and high blood pressure
- adrenal glands not working properly, which may cause weakness, tiredness, weight loss and low blood pressure
- bone thinning
- high pressure in the eye(s) (glaucoma)
- clouding of the lens of the eye (cataract) resulting in blurred vision
- slowing of growth in children and adolescents
- anxiety
- problems sleeping
- behavioural changes, including hyperactivity and irritability (mainly in children).

Frequency not known, but may also occur:

- depression, aggression. These effects are more likely to occur in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: [+353 1 6764971](tel:+35316764971); Fax: [+353 1 6762517](tel:+35316762517). Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Qvar Autohaler

Keep out of the reach and sight of children.

Do not store above 30°C. Do not expose to temperatures higher than 50°C. Storage in direct sunlight or heat should be avoided. Do not refrigerate or freeze. The canister contains a pressurised liquid. Do not pierce the canister.

Do not use Qvar Autohaler after the expiry date that is stated on the outer packaging (shown as 'EXP'). The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Your Qvar Autohaler 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 Autohaler contains

- The active ingredient is beclometasone dipropionate.
Qvar 50 Autohaler delivers 50 micrograms of beclometasone dipropionate per metered dose.

Qvar 100 Autohaler delivers 100 micrograms of beclometasone dipropionate per metered dose.

- The other ingredients are propellant HFA-134a and ethanol.

What Qvar Autohaler looks like and contents of the pack:

- Qvar Autohaler is an aluminium pressurised canister closed with a metering valve and supplied with a plastic actuator.
- Qvar Autohaler contains 100 or 200 metered doses.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Norton Waterford Limited
Trading as: IVAX Pharmaceuticals Ireland
Unit 301
Industrial Park
Waterford

Manufacturer:

3M Healthcare Ltd
Loughborough
LE11 1SL, UK

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