

Qvar[®] 100 micrograms Aerosol Inhaler (beclometasone dipropionate)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Your medicine is called Qvar 100 micrograms Aerosol Inhaler, but will be referred to as Qvar Aerosol throughout this leaflet. Please note that the leaflet also contains information about other strengths of the medicine, Qvar 50 micrograms Aerosol Inhaler.

In this leaflet:

1. What Qvar Aerosol is and what it is used for
2. Before you use Qvar Aerosol
3. How to use Qvar Aerosol
4. Possible side effects
5. How to store Qvar Aerosol
6. Further information

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

Qvar Aerosol contains beclometasone dipropionate, which is one of a group of medicines known as corticosteroids.

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

How your medicine works

- Qvar Aerosol 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. Before you use Qvar Aerosol

DO NOT use Qvar Aerosol if you:

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

Take special care with Qvar Aerosol

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

- you are suffering from tuberculosis (TB) now or have you 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.

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.

Taking other medicines

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

In particular tell your doctor if you are taking:

- Disulfiram
- Metronidazole.

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.

Driving and using machines

- Qvar Aerosol is not known to affect your ability to drive or operate machinery.

3. How to use Qvar Aerosol

There are two strengths of Qvar Aerosol available and your doctor will have chosen the strength which best suits your condition. Remember that it is important to use Qvar Aerosol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This inhaler has a softer feel and a different taste than CFC 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 previous CFC beclometasone dipropionate 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 previous CFC beclometasone dipropionate inhaler; this is because this inhaler may be a lower strength product (which means that each puff of this new inhaler contains less beclometasone dipropionate than your old CFC beclometasone dipropionate 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. The usual number of puffs to take is:

Qvar 50 Aerosol

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 100 Aerosol

Adults (including the elderly) and children over 12 years

- **Mild to 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.

Children under 12 years

Qvar Aerosol 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 Aerosol 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.

If you forget to use Qvar Aerosol

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 Aerosol

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.

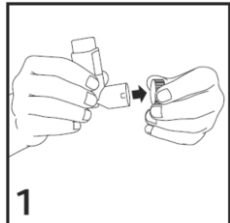
Using your Qvar Aerosol inhaler

Before Use:

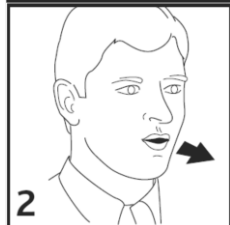
- If this is a new inhaler or if you have not used your inhaler for two weeks or more, it must be tested before use by removing the mouthpiece cover and pressing down on the canister inside the inhaler. Release 2 puffs into the air, away from you.

How to use your inhaler

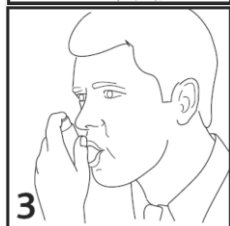
1. Take the cover off the mouthpiece



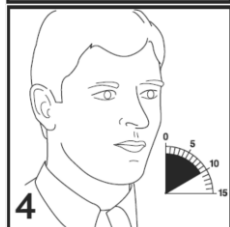
2. Breathe out as far as is comfortable and then immediately place the mouthpiece in your mouth and close your lips around it.



3. Start to breathe in slowly and deeply through your mouth and press down on the canister inside the inhaler as shown. This releases one puff of medicine. It is important that you carry on breathing in after the puff is released.



4. Hold your breath for 10 seconds, then breathe out slowly. If your doctor has prescribed more than one puff repeat steps 2 to 4 again. After use, replace the cover on the mouthpiece.



- **Some people find it difficult to press their inhaler and breathe in at the same time.** A spacer device helps to overcome this problem. The spacer that fits Qvar Aerosol is called the AeroChamber Plus[®] spacer device. If you use the AeroChamber Plus[®] spacer device, please follow the instructions provided with it. Your doctor, nurse or pharmacist will be able to advise you about the AeroChamber Plus[®] device.

Alternatively your doctor may wish to prescribe the Qvar Autohaler[®] device which automatically releases a puff of medication as you breathe in.

How to tell when your Qvar Aerosol device 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Qvar Aerosol 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.

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.

Treatment with Qvar Aerosol may affect the normal production of corticosteroids in the body. Keep **using your inhaler but see your doctor as soon as possible** if you become unwell, particularly with any of the following:

- abdominal pain
- weakness
- vomiting.

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

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

- hoarseness
- a 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 recommend a medicine to treat you
- feeling sick
- headache
- feeling dizzy or faint
- tremor
- change in taste
- increase in wheezing, shortness of breath and cough
- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children (Frequency not known).

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

- 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 may occur.

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 Aerosol.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Qvar Aerosol

- **Keep out of the sight and reach of children.**
- Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.
- Do not store above 25°C.
- The metal canister is pressurised, it should not be broken, punctured or burnt even when apparently empty.
- Protect from frost.
- Keep pressurised container away from heat and light.
- You can use your inhaler at temperatures as low as -10°C.
- The canister contains a pressurised liquid.
- Do not use Qvar Aerosol inhaler after the expiry date which is stated on the label and carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If your medicine shows any sign of deterioration, return it to your pharmacist.

6. Further Information

What Qvar Aerosol contains

- The active ingredient is beclometasone dipropionate.
- Each actuation contains 100 micrograms beclometasone dipropionate Ph Eur. as the active ingredients.
- Also contains norflurane (HFA 134a) and Ethanol.

What Qvar Aerosol looks like and contents of the pack

- Qvar Aerosol Inhaler is a colourless solution in a pressurised aluminium canister fitted with a metering valve and actuator, with a dark red body and grey cap.
- Your Inhaler contains 200 doses.
- The Qvar Aerosol Inhaler is packed in cartons containing one inhaler with 200 doses.

Manufacturer

This medicine is manufactured by 3M Health Care Limited, 1 Morley Street, Loughborough, Great Britain.

It is procured from within the EU by the Product Licence holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER, UK.

POM

Repackaged by: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Qvar 100 micrograms Aerosol Inhaler PL: 33532/0342

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, calls charged at local rates).

Leaflet dated 28th March 2013
Leaflet code XXXXXXXXX

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Autohaler[®] is a trademark of xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx