

Qvar™

Autohaler™ and Inhaler

(queue-var auto-hailer and queue-var in-hailer)

Beclometasone dipropionate extrafine aerosol (beck-low-meth-a-zone die-pro-pee-one-ate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about QVAR Autohaler and QVAR Inhaler. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking QVAR Autohaler and QVAR Inhaler against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What's in QVAR AUTOHALER and QVAR INHALER

The name of your medication is QVAR Autohaler and QVAR Inhaler. It contains an active ingredient called beclometasone dipropionate. Beclometasone dipropionate belongs to the corticosteroid family.

The amount of medicine in each puff of QVAR 50 Autohaler and QVAR 50 Inhaler is 50 micrograms of beclometasone dipropionate, and 100 micrograms in each puff of QVAR 100 Autohaler and QVAR 100 Inhaler.

Each QVAR Autohaler and QVAR Inhaler 200 dose contains at least 200 puffs.

What QVAR AUTOHALER and QVAR INHALER are used for

QVAR Autohaler and QVAR Inhaler are designed so the medicine can be inhaled (breathed in) into the lungs to help manage asthma.

Asthma causes the lining of your lungs to become inflamed (red and swollen), making it difficult for you to breathe.

Beclometasone dipropionate acts directly on your air passages to reduce inflammation. This helps to improve your condition and to prevent asthma attacks from occurring.

QVAR Autohaler and QVAR Inhaler are, therefore, known as a "PREVENTER" medicine.

It must be used every day even if you have no symptoms.

There is no evidence that QVAR Autohaler and QVAR Inhaler is addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

Before you use QVAR AUTOHALER or QVAR INHALER

When you must not use it

Do not use QVAR Autohaler and QVAR Inhaler if you have an allergy to:

- beclometasone dipropionate
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin

Do not use this medicine to treat an acute asthma attack.

Do not give this medicine to a child under the age of 5 years.

Safety and effectiveness in children younger than 5 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had tuberculosis (TB).

Tell your doctor or pharmacist if you currently have an infection.

Using QVAR Autohaler and QVAR Inhaler may hide some signs of infection. This could lead you to the mistaken belief that you are better or that the infection is not serious

Tell your doctor if you are pregnant or intend to become pregnant or you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist can discuss the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to use QVAR AUTOHALER and QVAR INHALER

Carefully follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

Even if you have been using another type of inhaler or Autohaler please read the instructions before you start.

If you do not understand the instructions or the pack or in this package insert ask your doctor or pharmacist for help.

QVAR AUTOHALER Instructions for Use

If your QVAR Autohaler is new or has not been used for two weeks or more you must test fire it by releasing two puffs into the air. QVAR Autohaler is designed for ease of use. To make it work you just breathe in through

the mouthpiece. There is no need to press and breathe in at the same time. A click and whoosh tells you that QVAR Autohaler has automatically released the correct dose of medicine.

There is no need to shake your QVAR AUTOHALER.

1. REMOVE THE MOUTHPIECE COVER

by unclipping it from the back.

2. HOLD UPRIGHT AND PUSH LEVER UP

Push the lever up so that it stays up. Keep holding the Autohaler unit upright making sure your hand is not blocking the air vent at the bottom

3. BREATHE OUT AND POSITION MOUTHPIECE.

Breathe out as far as you comfortably can and immediately close your lips around the mouthpiece.

4. BREATHE IN.

- Breathe in slowly and deeply through the mouthpiece.
- Do not stop breathing when you hear the 'click and whoosh' and feel the puff in your mouth. It is important to keep breathing in after the puff is released.

5. HOLD YOUR BREATH

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

6. PUSH LEVER DOWN.

- After each puff return the lever to the down position whilst holding the Autohaler unit upright.

If your doctor has prescribed more than one puff repeat steps 2 to 6.

Replace the mouthpiece cover after use.

Remember to push the lever up before each puff and gently back down afterwards, always holding the Autohaler upright. This prepares the Autohaler for your next dose. The lever should be left down between treatments and the mouthpiece replaced to keep your QVAR AUTOHALER clean.

How to test fire or how to tell if QVAR AUTOHALER is empty

1. REMOVE THE MOUTHPIECE COVER

by unclipping it from the back

2. Hold your QVAR Autohaler upright.

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

3. RELEASE A PUFF

by pushing the dose release slide (on the bottom of the Autohaler unit) in the direction of the arrow

4. TO RELEASE A SECOND PUFF

first return the lever to its down position, then repeat steps 2 and 3 as shown above

5. ALWAYS PUSH THE LEVER BACK DOWN

after test firing. This prepares the QVAR Autohaler for your next dose.

Do not use the dose release slide to take your medicine.

Your QVAR Autohaler will automatically release a dose when you begin to breathe in from the mouthpiece.

QVAR INHALER Instructions for Use

If this is a new QVAR Inhaler or if you have not used the QVAR Inhaler for 2 weeks or more it must be tested before use by releasing 2 puffs into the air away from your face.

There is no need to shake your QVAR INHALER.

1. CLEAR THE MOUTHPIECE

Remove the cover and check that the mouthpiece is clean.

2. BREATHE OUT

Hold your QVAR Inhaler upright and breathe out as far as you comfortably can.

3. POSITION THE MOUTHPIECE, BREATHE IN AND PRESS

Immediately close your lips around the mouthpiece. Start breathing in slowly, and firmly press the metal canister downwards until a puff is released. Complete your breath as fully and deeply as possible.

4. HOLD YOUR BREATH

Hold your breath for 10 seconds, then breathe out slowly. If another puff is needed, repeat steps 2 to 4. Always replace the mouthpiece cover after use.

How much to take

Use QVAR Autohaler or QVAR Inhaler only as directed by your doctor.

There are two strengths of QVAR Autohaler and QVAR Inhaler available and your doctor will have chosen the one which best suits your condition. Qvar is an extra fine aerosol, so more of each dose is delivered to your lungs. Because of this, your doctor may prescribe a lower dose of QVAR than your previous preventer inhaler.

Adults

With QVAR 50 Autohaler and QVAR 50 Inhaler, the usual dose in adults for mild to moderate asthma is one to four puffs twice a day. For more severe asthma the usual dose in adults is up to eight puffs twice a day.

With QVAR 100 Autohaler and QVAR 100 Inhaler, the usual dose in adults for mild to moderate asthma is one to two puffs twice a day. For more severe asthma the usual dose in adults is up to four puffs twice a day.

Your doctor will tell you which strength of QVAR Autohaler and QVAR Inhaler, to use and how many puffs to use each day.

Children

In children aged five years and over, the recommended dose of QVAR is one puff twice daily of QVAR 50 Autohaler and QVAR 50 Inhaler.

Children should be supervised by a responsible adult.

When to take it

Take your medicine at about the same times each day.

Using it at about the same times each day will have the best effect. It will also help you remember when to use it.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

If you forget to use it

Use it as soon as you remember and then go back to using it as you would normally. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Too much use of any asthma inhaler may be harmful.

Do not use more puffs than the recommended dose unless your doctor tells you to.

If you use too much QVAR Autohaler and QVAR Inhaler for a long time your adrenal glands (small glands above the kidneys) may not work as well as they should.

If you think you or anyone else may have used too much QVAR Autohaler and QVAR Inhaler, immediately telephone your doctor or pharmacist, or the Poisons Information Centre (in Australia call 13 11 26; in New Zealand call 0800 POISON or 0800 764 766). Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using QVAR AUTOHALER or QVAR INHALER

Things you must do

If you have an Asthma Management Plan follow it closely at all times.

Continue using QVAR Autohaler and QVAR Inhaler for as long as your doctor or pharmacist tells you. Visit your doctor regularly to check on your asthma condition.

If you suddenly find it more difficult to breathe just after using QVAR Autohaler and QVAR Inhaler, use a reliever inhaler and contact your doctor or pharmacist immediately.

QVAR Autohaler and QVAR Inhaler are used to PREVENT asthma attacks.

Always use QVAR Autohaler and QVAR Inhaler regularly as prescribed, even if you are not suffering any asthma symptoms.

If you think your asthma is getting worse (i.e. if you suffer more frequent asthma attacks) consult your doctor immediately.

If you are about to be started on any new medicine remind your doctor and pharmacist that you are using QVAR Autohaler and QVAR Inhaler.

Tell any other doctors, dentists or pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during the surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

Ask your doctor to regularly check the height of children and adolescents who are taking QVAR Autohaler and QVAR Inhaler.

Long term use of inhaled steroids may cause growth to be stunted.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

Things you must not do

Do not take any other medicines for your breathing problems without first checking with your doctor.

Do not give your medicine to anyone else to use, even if they have the same condition as you.

Do not use QVAR Autohaler and QVAR Inhaler to treat any other complaints unless your doctor or pharmacist tells you to do so.

Do not stop using QVAR Autohaler and QVAR Inhaler or lower the dose, without first checking with your doctor or pharmacist.

Do not use QVAR Autohaler and QVAR Inhaler to relieve acute attacks of asthma.

If you become wheezy or tight in the chest before your next dose is due, use a reliever inhaler in the usual way.

Do not use more puffs than you have been prescribed as this may cause you problems.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using QVAR Autohaler and QVAR Inhaler.

This medicine helps most people with asthma, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sore, creamy-yellow raised patches in the mouth (thrush), or a hoarse voice. These problems are less likely to occur if you rinse your mouth out with water each time after using QVAR Autohaler.
- narrowing of the airways, or chest tightness. This may happen if your lungs are very sensitive. If this occurs use a reliever inhaler. You may also prevent this effect by using your reliever inhaler before using your QVAR Autohaler and QVAR Inhaler. **If this effect is severe stop using it and see your doctor immediately.**
- a reduced growth rate or stunted growth in children and adolescents using QVAR Autohaler and QVAR Inhaler. Taking higher doses of inhaled steroids over a long time may cause them to grow more slowly than others. Ask your doctor to check their height regularly.

- blurred vision or other visual disturbances

See your doctor as soon as possible if you notice any of the following;

- allergic reactions such as:
 - rashes
 - itching
 - redness and swelling of the face, lips, mouth, throat and eyes may occur.

Very rarely this medicine may cause Cushing's syndrome (a condition of the adrenal gland) with the following symptoms: Cushingoid features such as round (moon-shaped) face, weight gain, high blood pressure, anxiety, sleeping disorders or increased irritability (mainly in children).

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using QVAR AUTOHALER or QVAR INHALER

Cleaning

Clean the mouthpiece once a week. For normal hygiene the mouthpiece should be cleaned with a clean dry tissue or cloth. DO NOT WASH OR PUT ANY PART OF YOUR AUTOHALER OR INHALER IN WATER.

It is important to keep your Autohaler or Inhaler device clean and dry. It may not work if it gets wet or dirty.

Remove the mouthpiece cover and wipe the mouthpiece with a clean dry cloth or tissue.

Do not push a cloth or anything else into any part of the device, since it may damage the operating parts. Do not take the device apart. Do not drop or hit the device. Always replace the mouthpiece cover after use.

Storage

Keep your QVAR Autohaler and QVAR Inhaler in a cool dry place where the temperature stays below 30°C.

Do not store QVAR Autohaler and QVAR Inhaler or any other medicine in the bathroom or near a sink.

Keep it away from direct heat and sunlight.

Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach.

A locked cupboard at least one-and-one-half metres above the ground is a good place to store medicines.

Protect QVAR Autohaler and QVAR Inhaler from frost.

Disposal

Do not puncture the container or throw it into the fire even when it is empty as the canister may explode.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

QVAR Autohaler consists of a metal canister sealed inside a plastic Autohaler unit. At the bottom of the Autohaler unit is a mouthpiece

with a plastic cover. At the top of the Autohaler unit is a grey lever.

QVAR Inhaler consists of a metal canister inside a plastic inhaler unit. At one end of the inhaler unit is a mouthpiece with a plastic cover.

Strengths

QVAR Autohaler and QVAR Inhaler come in two different strengths, 50 and 100 micrograms.

Each strength of QVAR Autohaler and QVAR Inhaler 200 dose contains at least 200 puffs.

Ingredients

Each puff of QVAR 50 Autohaler (AUST R 71991) or QVAR 50 Inhaler (AUST R 71992) releases 50 micrograms of beclometasone dipropionate.

Each puff of QVAR 100 Autohaler (Aust R 71994) or QVAR 100 Inhaler (Aust R 71993) releases 100 micrograms of beclometasone dipropionate.

QVAR Autohaler and QVAR Inhaler also contain:

- ethanol (0.0059mL per puff)
- norflurane (a non-CFC propellant which does not deplete ozone from the atmosphere).

Sponsor/Supplier

QVAR Autohaler and QVAR Inhaler are supplied by:

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539
Level 10, 12 Help Street
Chatswood NSW 2067
Australia

Australian Toll Free: 1800 630 056

New Zealand Toll Free: 0508 375 394

Developed and manufactured by:

3M Health Care Limited
Loughborough UK

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