Qvar® Autohaler® and Inhaler

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using QVAR?

QVAR contains the active ingredient beclometasone dipropionate. Beclometasone dipropionate is a corticosteroid that acts directly on your air passages to reduce inflammation. This helps to improve your condition and to prevent asthma attacks.

For more information, see Section <u>1. Why am I using</u> <u>QVAR?</u> in the full CMI.

2. What should I know before I use QVAR?

Do not use if you have ever had an allergic reaction to QVAR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use QVAR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QVAR and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use QVAR?

- Your doctor will prescribe the strength and dose of QVAR for you to take that best suit your condition.
- Follow all directions given by your doctor or other healthcare professionals and never change the dose yourself.

More instructions can be found in Section 4. How do I use QVAR? in the full CMI.

5. What should I know while using QVAR?

Things you should do

• Remind any doctor, dentist or pharmacist

you visit that you are using QVAR.

- If you are going to have surgery, tell the surgeon or anaesthetist that you are using QVAR.
- Do not use QVAR if you are pregnant, intend to become pregnant or breastfeeding.
- Continue using QVAR for as long as your doctor or pharmacist tells you. Visit your doctor regularly to check on your asthma condition.

Things you should not do

- Do not use QVAR to relieve acute attacks of asthma. Use a reliever inhaler as has been prescribed.
- Do not take any other medicines for your breathing problems without checking with your doctor.
- Do not use QVAR to treat any other conditions unless your

	doctor or pharmacist tells you to. • Do not stop using QVAR or lower the dose without checking with your doctor or pharmacist.
Looking after your medicine	 Keep your QVAR device clean and dry. It may not work if it gets wet or dirty. Do not wash or put any part of your QVAR device in water. Clean the mouthpiece with a clean dry cloth or tissue. Store in a cool dry place where the temperature stays below 30°C and keep out of reach of children.

For more information, see Section <u>5. What should I know while using QVAR?</u> in the full CMI.

6. Are there any side effects?

Less serious side effects include sore, creamy-yellow raised patches in the mouth (thrush), a hoarse voice, rashes, itching or irritation and redness and swelling of the face, lips, mouth, throat and eyes. Serious side effects include narrowing of the airways or chest tightness, changes to your eyesight or vision including blurred vision or other visual disturbances, stunted growth or a reduced growth rate in children and adolescents.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Qvar® Autohaler® and Inhaler

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

Active ingredient(s): Beclometasone dipropionate (beck-low-meth-a-zone die-pro-pee-one-ate)

Consumer Medicine Information (CMI)

This leaflet provides important information when using QVAR Autohaler or Qvar Inhaler. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions when using QVAR Autohaler or Qvar Inhaler.

Where to find information in this leaflet:

- 1. Why am I using QVAR?
- 2. What should I know before I use QVAR?
- 3. What if I am taking other medicines?
- 4. How do I use QVAR?
- 5. What should I know while using QVAR?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using QVAR?

QVAR contains the active ingredient beclometasone dipropionate.

Beclometasone dipropionate is a corticosteroid that acts directly on your air passages to reduce inflammation. This helps to improve your condition and to prevent asthma attacks.

QVAR is designed to enable the medicine to be inhaled into the lungs to help manage your asthma.

Asthma causes the lining of your lungs to become inflamed (red and swollen), making breathing difficult.

QVAR (sometimes also called a "PREVENTOR" medicine) is used to PREVENT asthma attacks and must be used every day even if you have no symptoms.

There is no evidence that QVAR is addictive.

2. What should I know before using QVAR?

Warnings

Do not use QVAR:

- If you are allergic to beclometasone dipropionate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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

- o rash, itching or hives on the skin.
- To treat an acute asthma attack
- After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- Have allergies to any other medicines, foods, preservatives or dyes
- Have or have previously suffered from tuberculosis
- Have an infection.
 - Using QVAR may mask some signs of an infection
- Have any other medical conditions or take any medicines for any other condition
- Are unsure whether you should start using QVAR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Do not use QVAR if you are pregnant or intend to become pregnant. QVAR may affect your developing baby if used during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Nursing mothers should avoid using QVAR as it is probable that the active ingredient, beclometasone dipropionate, passes into breast milk, and there is a possibility that your baby may be affected.

Use in children

Do not give QVAR to a child under the age of 5 years as the safety and effectiveness of QVAR in children younger than 5 years have not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with QVAR and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect QVAR.

4. How do I use QVAR?

How to use QVAR:

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

QVAR Autohaler and QVAR Inhaler both come in strengths of 50 micrograms per puff (QVAR 50) and 100 micrograms per puff (QVAR 100). Your doctor will have prescribed the strength 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.

Follow the instructions provided and use QVAR until your doctor tells you to stop.

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

<u>Adults</u>

- 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
- 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.

Children

- QVAR 50 Autohaler and QVAR 50 Inhaler: the recommended dose in children five years and over is one puff twice a day.
- Children should be supervised by a responsible adult when using QVAR.

When to use QVAR:

Taking QVAR at the same times each day will deliver the best effect for you and will also help you remember when to take it.

How long to use QVAR:

Continue using QVAR for as long as your doctor tells you. QVAR helps to control your condition but does not cure it. It is important to keep using QVAR even if you feel well or have no symptoms.

How to use QVAR:

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 autohaler or inhaler read the instructions in this leaflet before you start. If you do not understand the instructions, ask your doctor or pharmacist for help.

Qvar Autohaler Instructions for Use:

If this is a new QVAR Autohaler or has not been used for two weeks or more, you must test fire it by releasing two puffs into the air away from your face.

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 the QVAR Autohaler has automatically released the correct dose of medicine.

There is no need to shake the QVAR Autohaler.

STEP 1: Remove the Mouthpiece Cover:

By unclipping it from the back.

STEP 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.

STEP 3: Breathe Out and Position Mouthpiece:

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

STEP 4: Breath In:

Breath 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.

STEP 5: Hold Your Breathe:

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

STEP 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 Tell if Your Qvar Autohaler is Empty:

STEP 1: Remove the Mouthpiece Cover:

By unclipping it from the back.

STEP 2: Hold Your Qvar Autohaler Upright:

Point the mouthpiece away from you so that the puffs of medicines will go into the air.

STEP 3: Push the Lever Up:

So that it stays up.

STEP 4: Release a Puff:

By pushing the dose release slide (on the bottom of the autohaler unit) in the direction of the arrow.

STEP 5: To Release a Second Puff:

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

STEP 6: 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 has not been used for two weeks or more, you must test fire it by releasing two puffs into the air away from your face.

There is no need to shake the QVAR Inhaler.

STEP 1: Clear the Mouthpiece:

Remove the cover and check that the mouthpiece is clean.

STEP 2: Breath Out:

Hold the inhaler unit upright and breath out as far as you comfortably can.

STEP 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.

STEP 4: Hold Your Breathe:

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

If your doctor has prescribed more than one puff repeat steps 2 to 4.

Replace the mouthpiece cover after use.

If you forget to take QVAR:

QVAR should be used regularly at the same time each day.

If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take QVAR, ask your doctor or pharmacist for some hints.

If you take too much QVAR:

Too much use of any asthma inhaler may be harmful. If you think that you have taken too much QVAR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using QVAR?

Things you should do:

- If you have an Asthma Management Plan, always follow it closely.
- Always use QVAR regularly as prescribed, even if you are not suffering any asthma symptoms.
- Continue using QVAR for as long as your doctor or pharmacist tells you. Visit your doctor regularly to check on your asthma condition.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using QVAR. It may affect other medicines used during surgery.
- Ask your doctor to regularly check the height of children and adolescents who are using QVAR. Long term use of inhaled steroids may cause growth to be stunted.

Call your doctor straight away if you:

- Take your dose of QVAR and suddenly find it more difficult to breathe or tightness across your chest. Use a reliever inhaler and immediately contact your doctor or pharmacist.
- Think your asthma is getting worse (i.e. you suffer more frequent asthma attacks)
- Become pregnant while using QVAR.

If you are about to start on any new medicines, remind any doctor, dentist, or pharmacist you visit that you are using QVAR.

Things you should not do:

- Do not use QVAR 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 as prescribed.
- 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 to treat any other conditions unless your doctor or pharmacist tells you to do so.
- Do not stop using QVAR suddenly or lower the dose without first checking with your doctor or pharmacist
- Do not use more puffs than the recommended dose unless your doctor tells you to. If you use too much QVAR for a long time your adrenal glands (small glands above the kidneys) may not work as well as they should.

Driving or using machines:

Be careful before you drive or use any machines or tools until you know how QVAR affects you.

Drinking alcohol:

Tell your doctor if you drink alcohol.

Looking after your medicine:

Follow the instructions in the carton on how to take care of your medicine properly.

Cleaning

- Keep your QVAR Autohaler or Inhaler clean and dry.
 Do not wash it or put it in water. It may not work if it gets wet or dirty.
- Clean the mouthpiece once a week. Remove the mouthpiece cover and wipe it with a clean dry cloth or tissue.
- Do not push a cloth or anything else into any part of the device as this may damage the operating parts.
- Do not drop or hit the device or take it apart.
- Replace the mouthpiece cover after use.

Storage

Store below 30°C and protect from frost.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine:

Do not puncture the container or throw it into the fire even when it is empty as the canister may explode. If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Sore, creamy-yellow raised patches in the mouth (thrush) Hoarse voice 	Rinsing your mouth out with water after using QVAR can reduce these side effects.
	Speak to your doctor is you are worried about these less serious side effects.
RashesItching and irritation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
 Redness and swelling of the face, lips, mouth, throat and eyes 	

Serious side effects

Serious side effects	What to do
Narrowing of the airways or chest tightness (this may occur if your lungs are very sensitive)	 Use a reliever inhaler (using a reliever inhaler before using QVAR may also prevent this effect). If this effect is severe stop using QVAR. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Changes to your eyesight or vision including blurred vision or other visual disturbances (these may be signs of more serious issues)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
	notice any of these serious side effects.
Stunted growth or a reduced growth rate in children and adolescents that are using QVAR. Taking higher doses of inhaled steroids over a long time may cause children and adolescents to grow more slowly than others.	Speak to your doctor if you are worried and get them to check their height regularly.
Very rarely QVAR 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).	Speak to your doctor if you are worried and they can advise what you need to do.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What QVAR contains:

Active ingredient (main ingredient)	Beclometasone dipropionate
Other ingredients	Ethanol
(inactive ingredients)	Norflurane
Potential allergens	Ethanol

Do not take this medicine if you are allergic to any of these ingredients.

What QVAR looks like:

QVAR 50 AUTOHALER* and QVAR 100

AUTOHALER* are colourless solutions supplied in a metal canister 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. Each canister of QVAR Autohaler contains at least 200 puffs.

Australian registration numbers:

QVAR 50 Autohaler: AUST R 71991

Qvar 100 Autohaler: AUST R 71994

QVAR 50 INHALER and QVAR 100 INHALER are colourless solutions supplied in a metal canister inside a plastic inhaler unit. At one end of the inhaler unit is a mouthpiece with a plastic cover. Each canister of QVAR Inhaler contains at least 200 puffs.

Australian registration numbers:

QVAR 50 Inhaler: AUST R 71992

Qvar 100 Inhaler: AUST R 71993

* Not available in New Zealand

Who distributes QVAR:

Australia

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New Zealand

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