

Attention Pharmacist: Detach “Patient Information and Instructions for Use” from package insert and dispense with the product.

Patient Information
QVAR[®] (Kyu-var)
(beclomethasone dipropionate HFA)
inhalation aerosol

What is QVAR?

QVAR is an inhaled prescription medicine used as a maintenance treatment for the prevention and control of asthma in people 5 years of age and older.

- QVAR is not used to relieve sudden breathing problems.

It is not known if QVAR is safe and effective in children less than 5 years of age.

Who should not use QVAR?

Do not use QVAR:

- to treat sudden severe symptoms of asthma.
- as a rescue inhaler.
- if you are allergic to beclomethasone dipropionate or any of the ingredients in QVAR. See the end of this leaflet for a complete list of ingredients in QVAR.

What should I tell my healthcare provider before using QVAR?

Before using QVAR, tell your healthcare provider about all of your medical conditions, including if you:

- are exposed to chickenpox or measles
- have or have had tuberculosis (TB) or any untreated fungal, bacterial or viral infections, or eye infections caused by herpes.
- have weak bones (osteoporosis).
- have an immune system problem
- have or have had eye problems, such as blurred vision, increased pressure in your eye (glaucoma), or cataracts.

- are pregnant or plan to become pregnant. It is not known if QVAR will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if QVAR passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use QVAR.

Tell your healthcare provider about all of the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use QVAR?

Read the step-by-step instructions for using QVAR at the end of this Patient Information leaflet.

- Use QVAR exactly as your healthcare provider tells you to. **Do not** use QVAR more often than it is prescribed.
- **Do not** change or stop using QVAR or other asthma medicines used to treat your breathing problems unless your healthcare provider tells you to. Your healthcare provider will change your medicines as needed.
- You must use QVAR regularly. It may take 1 to 4 weeks, or longer, after you start using QVAR for your asthma symptoms to get better. **Do not** stop using QVAR, even if you are feeling better, unless your healthcare provider tells you to.
- QVAR comes in 2 strengths (40 and 80 mcg). Your healthcare provider has prescribed the strength that is best for you. Pay attention to the differences between QVAR and your other inhaled medicines, including their prescribed use and the way they look.
- QVAR does not relieve sudden asthma symptoms. Always have a rescue inhaler with you to treat sudden symptoms. Use your rescue inhaler if you have breathing problems between doses of QVAR. If you do not have a rescue inhaler, call your healthcare provider to have a rescue inhaler prescribed for you.
- Rinse your mouth with water **without swallowing** after each dose of QVAR. This will help lessen the chance of getting a yeast infection (thrush) in your mouth and throat.
- **Do not** spray QVAR in your face or eyes. If you accidentally get QVAR in your eyes, rinse your eyes with water and if redness or irritation continues, call your healthcare provider.

What should I avoid while using QVAR?

If you have not had, or have not been vaccinated against, chickenpox or measles, you should stay away from people who are infected.

What are the possible side effects of QVAR?

QVAR may cause serious side effects, including:

- **fungal infections (thrush) in your mouth and throat.** You may develop a yeast infection (*Candida albicans*) in your mouth and throat. Tell your healthcare provider if you have any redness or white colored patches in your mouth or throat. Rinse your mouth with water without swallowing after using QVAR to help prevent an infection in your mouth or throat.
- **worsening asthma or sudden asthma attacks.** You should contact your healthcare provider right away if you do not get relief from your sudden asthma attacks, after using your rescue inhaler, during your treatment with QVAR.
- **reduced adrenal function (adrenal insufficiency).** Adrenal insufficiency that can lead to death can happen when you stop taking oral corticosteroid medicines and start using inhaled corticosteroid medicines. Adrenal insufficiency can also happen in people who take higher doses of QVAR than recommended over a long period of time. When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse. Signs and symptoms of adrenal insufficiency may include:
 - feeling tired or exhausted (fatigue)
 - lack of energy
 - weakness
 - dizziness or feeling faint
 - nausea and vomiting
 - low blood pressure (hypotension)
- **immune system effects and a higher chance for infections.** Tell your healthcare provider about any signs or symptoms of infection such as:
 - fever
 - pain
 - body aches
 - chills
 - feeling tired
 - nausea
 - vomiting
- **increased wheezing (bronchospasm) right after using QVAR.** Always have a rescue inhaler with you to treat sudden wheezing.

- **serious allergic reactions.** Stop using QVAR and call your healthcare provider or get emergency medical help right away if you get any of the following signs or symptoms of an serious allergic reaction:
 - hives
 - swelling of your lips, tongue, or face
 - rash
 - breathing problems
- **slowed growth in children.** Children should have their growth checked regularly while using QVAR.
- **lower bone density.** This may be a problem for people who already have a higher chance for low bone density (osteoporosis).
- **eye problems.** If you have had glaucoma, cataracts or blurred vision in the past, you should have regular eye exams while using QVAR.

The most common side effects of QVAR include:

- headache
- throat irritation (pharyngitis)
- sinus irritation (sinusitis)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of QVAR. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store QVAR?

- Store QVAR at room temperature between 68°F to 77°F (20°C to 25°C).
- **Your QVAR canister should only be used with the QVAR actuator. Do not use any other medicines in your QVAR actuator.**
- The contents of your QVAR canister are under pressure. **Do not** puncture the QVAR canister.
- **Do not** store your QVAR canister near heat or a flame. Temperatures above 120°F may cause the canister to burst.
- **Do not** throw your QVAR canister into a fire or incinerator.
- When not in use, store QVAR so that the product rests on the concave end of the canister with the plastic actuator on top.

Keep QVAR and all medicines out of the reach of children.

General information about the safe and effective use of QVAR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use QVAR for a condition for which it was not prescribed. Do not give QVAR to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about QVAR that is written for health professionals.

What are the ingredients in QVAR?

Active ingredient: beclomethasone dipropionate

Inactive ingredients: propellant HFA-134a and ethanol

For more information, go to www.QVAR.com or call 1-888-482-9522.

QVAPL-003

Instructions for Use
QVAR (Kyu-var)
(beclomethasone dipropionate HFA)
inhalation aerosol

It is important that you read these instructions before using QVAR.

Correct and regular use of the inhaler will prevent or lessen the severity of asthma attacks.

- **Do not** use the QVAR actuator with a canister of medicine from any other inhaler.
- **Do not** use a QVAR canister with an actuator from any other inhaler, including another QVAR inhaler.

The parts of your QVAR:

- There are 2 main parts of your QVAR inhaler including the:
 - metal canister that holds the medicine (See Figure A)
 - plastic actuator that sprays the medicine from the canister (See Figure A)

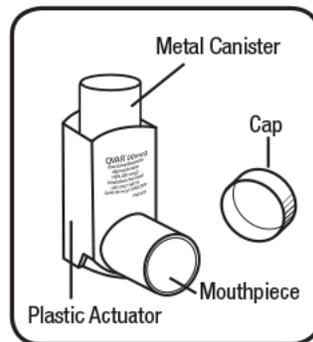


Figure A

- The inhaler has a cap that covers the mouthpiece of the actuator to protect it from dust(See Figure A). The cap should be removed before use.
- The inhaler comes with a dose counter located on the back of the actuator (See Figure B). The dose counter window will show you the number of actuations (puffs) of medicine remaining in units of **2**. The inhaler contains "**120**" actuations (puffs).

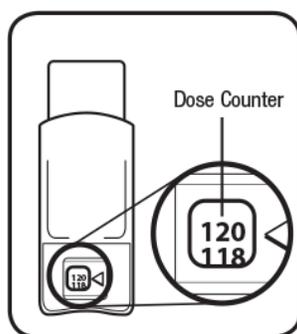


Figure B

- The first time you use QVAR inhaler, the dose counter will show “**120**” actuations remaining (See Figure B). Each time you press the metal canister, a puff of medicine is released and the dose counter will count down.
- When the dose counter reaches 0, it will continue to show 0 and you should replace your QVAR inhaler.
- The dose counter cannot be reset and is permanently attached to the actuator. Never change the numbers for the dose counter or touch the pin inside the actuator.

Do not remove the metal canister from the plastic actuator.

Before using your QVAR inhaler:

Remove the cap from the mouthpiece of the actuator (See Figure C).

Check the mouthpiece for objects before use. Make sure the metal canister is fully inserted into the actuator.

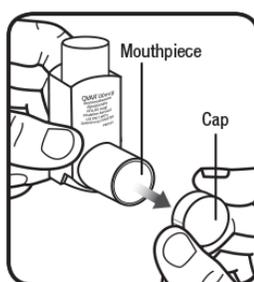


Figure C

Priming your QVAR inhaler:

Before you use your QVAR inhaler for the first time or if you have not used your QVAR Inhaler for more than 10 days, you will need to prime your QVAR Inhaler.

- Before priming, the inhaler will show a black dot in the dose counter window (See Figure D).

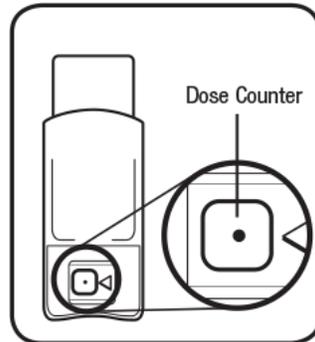


Figure D

- Hold the QVAR Inhaler in the upright position and with the mouthpiece pointing away from you.
- Press down on the metal canister **2** times and release **2** actuations (puffs) into the air and away from your face.
- After priming 2 times, the dose counter should read "**120.**"
 - Your QVAR Inhaler is now ready to use.

Using your QVAR inhaler:

Step 1: Remove the cap from the mouthpiece of the actuator (See Figure C). Check the mouthpiece for objects before use. Make sure the metal canister is fully inserted into the actuator.

Step 2: Breathe out as fully as you comfortably can. Hold the inhaler in the upright position (See Figure E). Close your lips around the mouthpiece, keeping your tongue below it.

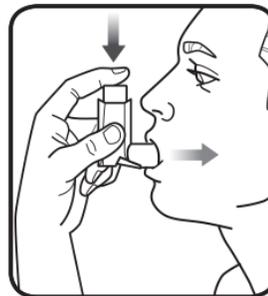


Figure E

Step 3: While breathing in deeply and slowly, press down on the metal canister with your finger (See Figure E). When you have finished breathing in, hold your breath as long as you comfortably can (5 to 10 seconds).

Step 4: Take your finger off the metal canister and remove the inhaler from your mouth. Breathe out gently.

If your healthcare provider has told you to take more than 1 inhalation per dose, repeat steps 1 through 4.

After using your QVAR inhaler:

- Replace the cap over the mouthpiece right away after use.
- You should rinse your mouth with water **without swallowing** after you finish using QVAR.
- Clean the mouthpiece of your QVAR inhaler weekly with a clean, dry tissue or cloth.
- **Do not** wash or put any part of your inhaler in water.

When to replace your QVAR Inhaler:

- It is important that you pay attention to the number of actuations (puffs) left in your QVAR inhaler by reading the dose counter.
- **When the dose counter on the actuator reads “20”**, the color of the number will change to red and you should refill your prescription or ask your healthcare provider if you need another prescription for QVAR Inhaler.
- When the dose counter reaches “0”, the background color in the dose counter window will change to solid red. **Throw away your QVAR inhaler** as soon as the dose counter reads “0” or by the expiration date on the QVAR Inhaler package, whichever comes first.
- **Do not** use QVAR past the expiration date.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

Marketed By:

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/s/

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