

PATIENT INFORMATION
QVAR REDIHALER (kue' var red-ee-haye' ler)
(beclomethasone dipropionate HFA) inhalation aerosol

What is QVAR REDIHALER?

QVAR REDIHALER is a breath-actuated inhaled prescription medicine used as a maintenance treatment for the prevention and control of asthma in people 4 years of age and older.

- QVAR REDIHALER is not used to relieve sudden breathing problems.

It is not known if QVAR REDIHALER is safe and effective in children less than 4 years of age.

Who should not use QVAR REDIHALER?

Do not use QVAR REDIHALER:

- 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 REDIHALER. See the end of this leaflet for a complete list of ingredients in QVAR REDIHALER.

What should I tell my healthcare provider before using QVAR REDIHALER?

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

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 REDIHALER?

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

- Use QVAR REDIHALER exactly as your healthcare provider tells you to. **Do not** use QVAR REDIHALER more often than it is prescribed.
- **Do not** shake the inhaler before using it. Especially, **do not** shake the inhaler with the cap open. This could cause the device to accidentally release medicine before you are ready to take it.
- You do not need to prime QVAR REDIHALER.
- If your child needs to use QVAR REDIHALER, watch your child closely to make sure your child uses the inhaler correctly.
- **Do not** change or stop using QVAR REDIHALER 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 REDIHALER regularly. It may take 2 to 4 weeks, or longer, after you start using QVAR REDIHALER for your asthma symptoms to get better. **Do not** stop using QVAR REDIHALER, even if you are feeling better, unless your healthcare provider tells you to.
- QVAR REDIHALER 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 REDIHALER and your other inhaled medicines, including their prescribed use and the way they look.
- QVAR REDIHALER 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 REDIHALER. 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 REDIHALER. This will help lessen the chance of getting a yeast infection (thrush) in your mouth and throat.
- **Do not** spray QVAR REDIHALER in your face or eyes. If you accidentally get QVAR REDIHALER in your eyes, rinse your eyes with water and if redness or irritation continues, call your healthcare provider.

What should I avoid while taking QVAR REDIHALER?

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 REDIHALER?**QVAR REDIHALER 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 REDIHALER 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 REDIHALER.
- **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 REDIHALER 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
 - low blood pressure (hypotension)
 - dizziness or feeling faint
 - nausea and vomiting
 - weakness
- **immune system effects and a higher chance for infections.** Tell your healthcare provider about any signs or symptoms of infection such as:
 - fever
 - chills
 - pain
 - feeling tired
 - body aches
 - nausea
 - vomiting
- **increased wheezing (bronchospasm) right after using QVAR REDIHALER.** Always have a rescue inhaler with you to treat sudden wheezing.
- **serious allergic reactions.** Stop using QVAR REDIHALER 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 REDIHALER.
- **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 REDIHALER.

The most common side effects of QVAR REDIHALER include:

- yeast infection in the mouth (oral candidiasis)
- cold symptoms (upper respiratory tract infection)
- pain in the throat (oropharyngeal pain)
- pain or swelling in your nose and throat (nasopharyngitis)
- sinus irritation (sinusitis)
- hay fever (allergic rhinitis)

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 REDIHALER. 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 REDIHALER?

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

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

General information about the safe and effective use of QVAR REDIHALER.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use QVAR REDIHALER for a condition for which it was not prescribed. Do not give QVAR REDIHALER 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 REDIHALER that is written for health professionals.

What are the ingredients in QVAR REDIHALER?

Active ingredient: beclomethasone dipropionate

Inactive ingredients: propellant HFA-134a and ethanol

For more information, go to www.QvarRedihaler.com or call 1-888-483-8279.