

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

PATIENT INFORMATION

Beclomethasone Dipropionate (be'' kloe meth' a sone dye proe' pee oh nate) HFA Inhalation Aerosol

What is beclomethasone dipropionate HFA inhalation aerosol?

Beclomethasone dipropionate HFA inhalation aerosol 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.

- Beclomethasone dipropionate HFA inhalation aerosol is not used to relieve sudden breathing problems.

It is not known if beclomethasone dipropionate HFA inhalation aerosol is safe and effective in children less than 5 years of age.

Who should not use beclomethasone dipropionate HFA inhalation aerosol?

Do not use beclomethasone dipropionate HFA inhalation aerosol:

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

What should I tell my healthcare provider before using beclomethasone dipropionate HFA inhalation aerosol?

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

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 beclomethasone dipropionate HFA inhalation aerosol?

Read the step-by-step instructions for using beclomethasone dipropionate HFA inhalation aerosol at the end of this Patient Information leaflet.

- Use beclomethasone dipropionate HFA inhalation aerosol exactly as your healthcare provider tells you to. **Do not** use beclomethasone dipropionate HFA inhalation aerosol more often than it is prescribed.
- **Do not** change or stop using beclomethasone dipropionate HFA inhalation aerosol 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 beclomethasone dipropionate HFA inhalation aerosol regularly. It may take 1 to 4 weeks, or longer, after you start using beclomethasone dipropionate HFA inhalation aerosol for your asthma symptoms to get better. **Do not** stop using beclomethasone dipropionate HFA inhalation aerosol, even if you are feeling better, unless your healthcare provider tells you to.
- Beclomethasone dipropionate HFA inhalation aerosol 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 beclomethasone dipropionate HFA inhalation aerosol and your other inhaled medicines, including their prescribed use and the way they look.
- Beclomethasone dipropionate HFA inhalation aerosol 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 beclomethasone dipropionate HFA inhalation aerosol. 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 beclomethasone dipropionate HFA inhalation aerosol. This will help lessen the chance of getting a yeast infection (thrush) in your mouth and throat.
- **Do not** spray beclomethasone dipropionate HFA inhalation aerosol in your face or eyes. If you accidentally get beclomethasone dipropionate HFA inhalation aerosol in your eyes, rinse your eyes with water and if redness or irritation continues, call your healthcare provider.

What should I avoid while using beclomethasone dipropionate HFA inhalation aerosol?

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 beclomethasone dipropionate HFA inhalation aerosol?

Beclomethasone dipropionate HFA inhalation aerosol 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 beclomethasone dipropionate HFA inhalation aerosol 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 beclomethasone dipropionate HFA inhalation aerosol.
- **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 beclomethasone dipropionate HFA inhalation aerosol 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** beclomethasone dipropionate HFA inhalation aerosol. Always have a rescue inhaler with you to treat sudden wheezing.
- **serious allergic reactions.** Stop using beclomethasone dipropionate HFA inhalation aerosol and call your healthcare provider or get emergency medical help right away if you get any of the following signs or symptoms of a 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 beclomethasone dipropionate HFA inhalation aerosol.
- **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 beclomethasone dipropionate HFA inhalation aerosol.

The most common side effects of beclomethasone dipropionate HFA inhalation aerosol 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 beclomethasone dipropionate HFA inhalation aerosol. 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 beclomethasone dipropionate HFA inhalation aerosol?

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

- **Do not** throw your beclomethasone dipropionate HFA inhalation aerosol canister into a fire or incinerator.
- When not in use, store beclomethasone dipropionate HFA inhalation aerosol so that the product rests on the concave end of the canister with the plastic actuator on top.

Keep beclomethasone dipropionate HFA inhalation aerosol and all medicines out of the reach of children.

General information about the safe and effective use of beclomethasone dipropionate HFA inhalation aerosol.

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

What are the ingredients in beclomethasone dipropionate HFA inhalation aerosol?

Active ingredient: beclomethasone dipropionate, USP

Inactive ingredients: propellant HFA-134a and ethanol

For more information, go to www.amneal.com or call 1-877-835-5472.

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