

PATIENT INFORMATION
Budesonide (bue des' oh nide)
delayed-release capsules

Read this Patient Information before you start taking budesonide delayed-release capsules and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What are budesonide delayed-release capsules?

Budesonide delayed-release capsules are a prescription corticosteroid medicine used to treat mild to moderate Crohn's disease that affects part of the small intestine (ileum) and part of the large intestine (ascending colon):

- in people 8 years of age and older with active Crohn's disease
- in adults to help keep symptoms from coming back for up to 3 months

It is not known if budesonide delayed-release capsules are safe and effective in children under 8 years of age, or in children 8 to 17 years of age who weigh 55 pounds (25 kg) or less, for the treatment of mild to moderate active Crohn's disease that affects part of the small intestine (ileum) and part of the large intestine (ascending colon).

It is not known if budesonide delayed-release capsules are safe and effective in children to help keep symptoms of mild to moderate Crohn's disease that affects part of the small intestine (ileum) and part of the large intestine (ascending colon) from coming back.

Who should not take budesonide delayed-release capsules?

Do not take budesonide delayed-release capsules if:

- you are allergic to budesonide or any of the ingredients in budesonide delayed-release capsules. See the end of this leaflet for a complete list of ingredients in budesonide delayed-release capsules.

Before you take budesonide delayed-release capsules tell your healthcare provider if you have any other medical conditions including if you:

- have liver problems.
- are planning to have surgery.
- have chicken pox or measles or have recently been near anyone with chicken pox or measles.
- have an infection, including fungal and threadworm (Strongyloides) infections.
- have diabetes or glaucoma or have a family history of diabetes or glaucoma.
- have cataracts.
- have or had tuberculosis.
- have high blood pressure (hypertension).
- have decreased bone mineral density (osteoporosis).
- have stomach ulcers.
- have malaria of the brain (cerebral malaria).
- are pregnant or plan to become pregnant. Budesonide delayed-release capsules may harm your unborn baby. Talk to your healthcare provider about the possible risk to your unborn baby if you take budesonide delayed-release capsules when you are pregnant. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during your treatment with budesonide delayed-release capsules.
- are breastfeeding or plan to breastfeed. It is not known if budesonide passes into your breast milk or if it will affect your baby. Talk to your healthcare provider about the best way to feed your baby if you take budesonide delayed-release capsules.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Budesonide delayed-release capsules and other medicines may affect each other causing side effects.

How should I take budesonide delayed-release capsules?

- Take budesonide delayed-release capsules exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how many budesonide delayed-release capsules capsules to take. Your healthcare provider may change your dose if needed.
- Take budesonide delayed-release capsules 1 time each day in the morning.
- Take budesonide delayed-release capsules whole. Do not chew or crush budesonide delayed-release capsules before swallowing.
- For patients, unable to swallow a whole capsule, budesonide delayed-release capsules can be opened and administered as follows:
 1. Place 1 tablespoonful of applesauce into a clean container, such as an empty bowl. The applesauce used should not be hot and should be soft enough to be swallowed without chewing.
 2. Open the capsule. You may need to use more than 1 budesonide delayed-release capsule for the dose prescribed by your healthcare provider.
 3. Carefully empty all of the granules inside the capsule on the applesauce.
 4. Stir the granules with the applesauce.
 5. Swallow the applesauce and granules mixture within 30 minutes after preparing it. Follow the applesauce and granules immediately with a glass (8 ounces) of cool water to help with complete swallowing of the granules.
 6. Do not chew or crush the granules.
 7. Do not save the applesauce and granules for later use.
- If you take too many budesonide delayed-release capsules call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking budesonide delayed-release capsules?

- Do not drink grapefruit juice during your treatment with budesonide delayed-release capsules. Drinking grapefruit juice can increase the level of budesonide in your blood.

What are the possible side effects of budesonide delayed-release capsules?

- **Budesonide delayed-release capsules may cause serious side effects, including:**
- **Effects of having too much corticosteroid medicine in your blood (hypercorticism).** Long-time use of budesonide delayed-release capsules can cause you to have too much corticosteroid medicine in your blood.

Tell your healthcare provider if you have any of the following signs and symptoms of hypercorticism:

- acne
- bruise easily
- rounding of your face (moon face)
- ankle swelling
- thicker or more hair on your body and face
- a fatty pad or hump between your shoulders (buffalo hump)
- pink or purple stretch marks on the skin of your abdomen, thighs, breasts and arms

- **Adrenal suppression.** When budesonide delayed-release capsules are taken for a long period of time (chronic use), adrenal suppression can happen. This is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal suppression include: tiredness, weakness, nausea and vomiting and low blood pressure. Tell your healthcare provider if you are under stress or have any symptoms of adrenal suppression during treatment with budesonide delayed-release capsules.

- **Worsening of allergies.** If you take certain other corticosteroid medicines to treat allergies, switching to budesonide delayed-release capsules may cause your allergies to come back. These allergies may include a skin condition called eczema or inflammation inside your nose (rhinitis). Tell your healthcare provider if any of your allergies become worse while taking budesonide delayed-release capsules.

- **Decreased ability of your body to fight infections (immunosuppression) and increased risk of infection.**

Corticosteroid medicines, including budesonide delayed-release capsules, lower the ability of your immune system to fight infections and increase the risk of infections caused by virus, bacteria, fungi, protozoan, or certain parasites. Corticosteroid medicines including budesonide delayed-release capsules can also:

- make current infections worse
- increase the risk of infections spreading (disseminated)
- increase the risk of making infections active again or making infections worse that have not been active (latent)
- hide (mask) some signs of infection

These infections can be mild, but can be severe and lead to death. Your healthcare provider should check you closely for signs and symptoms of an infection while taking budesonide delayed-release capsules. Tell your healthcare provider right away about any signs or symptoms of a new or worsening infection while taking budesonide delayed-release capsules, including flu-like symptoms such as:

- fever
- chills
- stomach area (abdominal) pain
- aches
- diarrhea
- cough
- pain
- feeling tired
- nausea and vomiting
- Tuberculosis: If you have inactive (latent) tuberculosis, your tuberculosis may become active again while taking budesonide delayed-release capsules your healthcare provider should check you closely for signs and symptoms of tuberculosis while taking budesonide delayed-release capsules.
- Chicken pox and measles: People taking corticosteroid medicines, including budesonide delayed-release capsules, who have not had chicken pox or measles, should avoid contact with people who have these diseases. Tell your healthcare provider right away if you come in contact with anyone who has chicken pox or measles.
- Hepatitis B Virus (HBV) reactivation: If you are a carrier of HBV, the virus can become an active infection again while taking budesonide delayed-release capsules. Your healthcare provider will test you for HBV before you start taking budesonide delayed-release capsules.
- Amebiasis: Inactive (latent) amebiasis before you start taking budesonide delayed-release capsules. Your healthcare provider should check you for amebiasis before you start taking budesonide delayed-release capsules in people who have spent time in the tropics or have unexplained diarrhea.
- **Kaposi's Sarcoma.** Kaposi's sarcoma has happened in people who receive corticosteroid therapy, most often for treatment of long-lasting (chronic) conditions.

The most common side effects of budesonide delayed-release capsules in adults include:

- headache
- stomach area (abdominal) pain
- infection in your air passages (respiratory infection)
- gas
- nausea
- vomiting
- back pain
- tiredness
- indigestion
- pain
- dizziness

The most common side effects of budesonide delayed-release capsules in children 8 to 17 years of age, who weigh more than 55 pounds (25 kg), are similar to the most common side effects in adults.

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 budesonide delayed-release capsules. For more information, ask your healthcare provider or pharmacist.

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 budesonide delayed-release capsules?

- Store budesonide delayed-release capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep budesonide delayed-release capsules in a tightly closed container.

Keep budesonide delayed-release capsules and all medicines out of the reach of children.

General information about the safe and effective use of budesonide delayed-release capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide or Patient Information leaflet. Do not use budesonide delayed-release capsules for a condition for which it was not prescribed. Do not give budesonide delayed-release capsules 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 budesonide delayed-release capsules that is written for health professionals.

What are the ingredients in budesonide delayed-release capsules?

Active ingredient: budesonide

Inactive ingredients: ethylcellulose, acetyltributyl citrate, methacrylic acid copolymer type C, triethyl citrate, antifoam M, polysorbate 80, talc, and sugar spheres. The capsule shell contains: gelatin, iron oxide, and titanium dioxide.

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For more information, go to www.padagis.com or call 1-866-634-9120.

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