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Patient Information
Budesonide Extended-Release Tablets
(bue des' oh nide)

What are budesonide extended-release tablets?

- Budesonide extended-release tablets are a prescription corticosteroid medicine used to help get active mild to moderate ulcerative colitis (UC) under control (induce remission).
- It is not known if budesonide extended-release tablets are safe and effective in children.

Who should not take budesonide extended-release tablets?

Do not take budesonide extended-release tablets if:

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

What should I tell my healthcare provider before taking budesonide extended-release tablets?

Before you take budesonide extended-release tablets tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.
- are planning to have surgery.
- have chickenpox or measles or have recently been near anyone with chickenpox or measles.
- have an infection.
- have or had a family history of diabetes, cataracts or glaucoma.
- have or had tuberculosis.
- have high blood pressure (hypertension).
- have decreased bone mineral density (osteoporosis).
- have stomach ulcers.
- are pregnant or plan to become pregnant. Budesonide extended-release tablets may harm your unborn baby. Tell your healthcare provider if you are pregnant or think you are pregnant.
- are breastfeeding or plan to breastfeed. Budesonide can pass into your breast milk and may harm your baby. You and your healthcare provider should decide if you will take budesonide extended-release tablets or breastfeed. You should not do both.

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

Especially tell your healthcare provider if you take another medicine that contains corticosteroids for other conditions, such as allergies or asthma.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take budesonide extended-release tablets?

- Take budesonide extended-release tablets exactly as your healthcare provider tells you to take them.
- Take budesonide extended-release tablets 1 time each day in the morning with or without food.
- Take budesonide extended-release tablets whole with water. Do not chew, crush, or break budesonide extended-release tablets before swallowing.
- If you take too many budesonide extended-release tablets, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking budesonide extended-release tablets?

- Do not eat grapefruit or drink grapefruit juice while taking budesonide extended-release tablets. Eating grapefruit or drinking grapefruit juice can increase the level of budesonide in your blood.

What are the possible side effects of budesonide extended-release tablets?

Budesonide extended-release tablets may cause serious side effects, including:

- **Effects of having too much corticosteroid medicine in your blood (hypercorticism).** Long-time use of budesonide extended-release tablets can cause you to have too much glucocorticosteroid 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 extended-release tablets are taken for a long period of time (chronic use), the adrenal glands do not make enough steroid hormones (adrenal suppression). Tell your healthcare provider if you are under stress or have any symptoms of adrenal suppression during treatment with budesonide extended-release tablets including:
 - tiredness
 - weakness
 - nausea
 - vomiting
 - low blood pressure
- **Immune system effects and a higher chance of infections.** Budesonide extended-release tablets weaken your immune system. Taking medicines that weaken your immune system makes you more likely to get infections. Avoid contact with people who have contagious diseases such as chickenpox or measles, while taking budesonide extended-release tablets. Tell your healthcare provider about any signs or symptoms of infection during treatment with budesonide extended-release tablets, including:
 - fever
 - pain
 - aches
 - chills
 - feeling tired
 - nausea and vomiting
- **Worsening of allergies.** If you take certain other corticosteroid medicines to treat allergies, switching to budesonide extended-release tablets may cause your allergies to come back. These allergies may include eczema (a skin disease) or rhinitis (inflammation inside your nose). Tell your healthcare provider if any of your allergies become worse while taking budesonide extended-release tablets.

The most common side effects of budesonide extended-release tablets include:

- headache
- stomach or intestinal gas
- nausea
- bloating
- decreased blood cortisol levels
- acne
- stomach-area pain
- urinary tract infection
- tiredness
- joint pain
- constipation

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 extended-release tablets. 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 extended-release tablets?

- Store budesonide extended-release tablets at room temperature, between 20° to 25°C (68° to 77°F).
- Keep the bottle tightly closed to protect budesonide extended-release tablets from light and moisture.

Keep budesonide extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of budesonide extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use budesonide extended-release tablets for a condition for which they were not prescribed. Do not give budesonide extended-release tablets to other people, even if they have the same symptoms you have. They may harm them.

You can ask your healthcare provider or pharmacist for information about budesonide extended-release tablets that is written for health professionals.

For more information, call Mylan at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in budesonide extended-release tablets?

Active ingredient: budesonide

Inactive ingredients: colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer type A and type B, microcrystalline cellulose, polyethylene glycol, polydextrose, talc, titanium dioxide, triacetin and triethyl citrate.

In addition, the black imprinting ink contains black iron oxide, hypromellose and propylene glycol.

Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

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



Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

Revised: 4/2020
BUDEERT:R4