Read the Patient Information that comes with budesonide capsules (enteric coated) before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What are budesonide capsules (enteric coated)?
Budesonide capsules (enteric coated) are a prescription glucocorticosteroid medicine used in people with mild to moderate Crohn’s disease that affects part of the small intestine (ileum) and part of the large intestine (ascending colon):
• to treat active Crohn’s disease
• to help keep symptoms from coming back for up to 3 months. It is not known if budesonide capsules (enteric coated) are safe and effective in children.

Who should not take budesonide capsules (enteric coated)?
Do not take budesonide capsules (enteric coated) if:
• you are allergic to budesonide or any of the ingredients in budesonide capsules (enteric coated). See the end of this leaflet for a complete list of ingredients in budesonide capsules (enteric coated).

What should I tell my healthcare provider before taking budesonide capsules (enteric coated)?
Before you take budesonide capsules (enteric coated) tell your healthcare provider 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 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)
• stomach ulcers
• any other medical condition
• are pregnant or plan to become pregnant. It is not known if budesonide capsules (enteric coated) may harm your unborn baby.
• are breastfeeding or plan to breastfeed. Budesonide can pass into breast milk and may harm your baby. You and your healthcare provider should decide if you will take budesonide capsules (enteric coated) or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Budesonide capsules (enteric coated) and other medicines may affect each other causing side effects. Especially tell your healthcare provider if you take:
• a glucocorticosteroid medicine
• medicines that suppress your immune system (immunosuppressant)
• ketoconazole or other medicines that affect how your liver works.

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one listed above.

How should I take budesonide capsules (enteric coated)?
• Take budesonide capsules (enteric coated) exactly as your healthcare provider tells you.
• Your healthcare provider will tell you how many budesonide capsules (enteric coated) to take. Your healthcare provider may change your dose if needed.
• Take budesonide capsules (enteric coated) in the morning.
• Take budesonide capsules (enteric coated) whole. Do not chew or crush budesonide capsules (enteric coated) before swallowing.

What should I avoid while taking budesonide capsules (enteric coated)?
• Do not eat grapefruit or drink grapefruit juice while taking budesonide capsules (enteric coated). Eating grapefruit or drinking grapefruit juice can increase the level of budesonide in your blood.

What are the possible side effects of budesonide capsules (enteric coated)?
• Effects of having too much glucocorticosteroid medicine in your blood (hypercorticism). Long-time use of budesonide capsules (enteric coated) 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 capsules (enteric coated) 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 capsules (enteric coated).

- **Immune system effects and a higher chance of infections.** Budesonide capsules (enteric coated) 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 chicken pox or measles, while taking budesonide capsules (enteric coated).
  
  Tell your healthcare provider about any signs or symptoms of infection during treatment with budesonide capsules (enteric coated), including:
  
  - fever
  - pain
  - aches
  - chills
  - feeling tired
  - nausea and vomiting

- **Worsening of allergies.** If you take certain other glucocorticosteroid medicines to treat allergies, switching to budesonide capsules (enteric coated) 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 capsules (enteric coated).

The most common side effects of budesonide capsules (enteric coated) include:

- headache
- infection in your air passages (respiratory infection)
- back pain
- abdominal pain
- excessive stomach or intestinal gas
- diarrhea
- sinus infection
- viral infection
- joint pain

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 capsules (enteric coated). For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**How should I store budesonide capsules (enteric coated)?**

- Store budesonide capsules (enteric coated) at 20° to 25°C (68° to 77°F).
- Keep budesonide capsules (enteric coated) in a tightly closed container.

Keep budesonide capsules (enteric coated) and all medicines out of reach from children.

**General information about budesonide capsules (enteric coated).**

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use budesonide capsules (enteric coated) for a condition for which it was not prescribed. Do not give budesonide capsules (enteric coated) to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about budesonide capsules (enteric coated). If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about budesonide capsules (enteric coated) that is written for health professionals.

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

**What are the ingredients in budesonide capsules (enteric coated)?**

Active ingredient: budesonide, USP

Inactive ingredients: acetyltributyl citrate, colloidal silicon dioxide, crospovidone, dimethicone, ethylcellulose, FD&C Red No. 40 Aluminum Lake, gelatin, lactose monohydrate, magnesium stearate, methacrylic acid copolymer type C, polysorbate 80, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide and triethyl citrate.

The imprinting ink contains the following: black iron oxide, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, Propylene Glycol and shellac glaze.

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

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

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