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PATIENT INFORMATION

Budesonide (bue-des-oh-nide) extended-release Capsules (Enteric Coated)

Rx Only

Read this Patient Information before you start taking budesonide capsules (enteric coated) 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 capsules (enteric coated)?

Budesonide capsules (enteric coated) 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 capsules (enteric coated) 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 capsules (enteric coated) is 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 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 an infection.
- 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 any other medical condition.
- are pregnant or plan to become pregnant. Budesonide capsules (enteric coated) may harm your unborn baby. Talk to your healthcare provider about the possible risk to your unborn baby if you take budesonide capsules (enteric coated) 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 capsules (enteric coated).
- are breastfeeding or plan to breastfeed. It is not known if budesonide capsules (enteric coated) 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 capsules (enteric coated).

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

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) 1 time each day in the morning.
- Take budesonide capsules (enteric coated) whole. Do not chew or crush budesonide capsules (enteric coated) before swallowing.
- If you take too much budesonide capsules (enteric coated) call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking budesonide capsules (enteric coated)?

- Do not drink grapefruit juice during your treatment with budesonide capsules (enteric coated). Drinking grapefruit juice can increase the level of budesonide capsules (enteric coated) in your blood.

What are the possible side effects of budesonide capsules (enteric coated)?

Budesonide capsules (enteric coated) may cause serious side effects, including:

- **Effects of having too much corticosteroid medicine in your blood (hypercorticism).** Long-time use of budesonide capsules (enteric coated) 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 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).
- **Worsening of allergies.** If you take certain other corticosteroid medicines to treat allergies, switching to budesonide capsules (enteric coated) 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 capsules (enteric coated).
- **Increased risk of infection.** Budesonide capsules (enteric coated) weakens 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 right away if you come in contact with anyone who has chicken pox or measles.

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

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

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

The most common side effects of budesonide capsules (enteric coated) 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 capsules (enteric coated). 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 or www.fda.gov/medwatch. You may also report side effects to Mayne Pharma at 1-844-825-8500.

How should I store budesonide capsules (enteric coated)?

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

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

General information about the safe and effective use of budesonide capsules (enteric coated).

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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. You can ask your healthcare provider or pharmacist for information about budesonide capsules (enteric coated) that is written for health professionals.

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

Active ingredient: budesonide

Inactive ingredients: acetyltributyl citrate, ethylcellulose, hypromellose, methacrylic acid copolymer (type C powder), polyethylene glycol, polysorbate 80, sodium lauryl sulfate, sugar spheres (sucrose and corn starch), talc, and triethyl citrate. The capsule shell has the following inactive ingredients gelatin, D&C red #28, D&C red #33, and titanium dioxide. In addition, the black ink S-1-8114/S-1-8115 contains, black iron oxide, D&C yellow #10 aluminum lake, FD&C blue#1 brilliant blue FCF aluminum lake, FD&C blue #2 indigo carmine aluminum lake, FD&C red #40 allura red AC aluminum lake, propylene glycol, and shellac.

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For more information contact Mayne Pharma at 1-844-825-8500.

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

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