budesonide (oral) (byoo-dess-o-nide)

**Entocort EC, Uceris**

**Classification**
- Gastrointestinal anti-inflammatories
- Pharmacologic: corticosteroids

**Pregnancy Category C**

**Indications**

**Entocort EC**
- Treatment of mild to moderate active Crohn's disease involving ileum and/or ascending colon.
- Maintenance of clinical remission for up to 3 mos of mild to moderate Crohn's disease involving ileum and/or ascending colon.

**Uceris**
- Induction of remission of active, mild to moderate ulcerative colitis.

**Action**
- Has high local anti-inflammatory activity in the lumen of the GI tract, but is rapidly inactivated following absorption. Action is primarily local. Formulation resists acid degradation in the stomach and then releases budesonide slowly throughout the GI tract.

**Therapeutic Effects:**
- Improvement in symptoms/sequelae of Crohn’s disease (decreased frequency of liquid stools, decreased abdominal complaints, improved sense of well-being).
- Induction of remission of ulcerative colitis.

**Pharmacokinetics**

**Absorption:** Well absorbed following oral administration (9–21% bioavailability).

**Distribution:** 2.2–3.9 L/kg; enters breast milk.

**Protein Binding:** 85–90%.

**Metabolism and Excretion:** Rapidly and extensively metabolized during first pass hepatic metabolism by the CYP3A4 enzyme system to inactive metabolites which are excreted in urine and feces.

**Half-life:** 2.0–3.6 hr.

**TIME/ACTION PROFILE (improvement in symptoms of Crohn's disease or induction of remission of ulcerative colitis)**

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**Contraindications/Precautions**

**Contraindicated in:** Known hypersensitivity.

**Use Cautiously in:** History of diabetes (or family history), tuberculosis, osteoporosis, hypertension, peptic ulcer, glaucoma (or family history) or cataracts (conditions may be exacerbated); Stress, including surgery or infections; supplemental doses of corticosteroid may be needed; Active untreated infections; Immunosuppression; Potentially infectious (may mask signs such as fever or inflammation); Moderate to severe liver disease (dose may be necessary); OB, Pedi: Safety not established; Geri: ↑ risk of adverse reactions.

**Adverse Reactions/Side Effects**

- **CNS:** headache, agitation, confusion, drowsiness, depression, fatigue, ↑ appetite, insomnia, nervousness, séducts.
- **EENT:** abnormal vision, conjunctivitis.
- **Resp:** bronchitis, dyspnea.
- **CV:** edema, hypertension, palpitations, tachycardia.
- **GI:** nausea, abdominal pain, dyspepsia, flatulence, vomiting.
- **GU:** dysuria, irregular menses, nocturia, urinary frequency.
- **Derm:** acne, easy bruising, hirsutism, alopecia, dermatitis, eczema, flushing, pruritus.
- **Endo:** adrenal suppression, hypokalemia.
- **Hemat:** leukocytosis.
- **Metab:** weight gain.
- **Neuro:** hyperkinesia, paraesthesia, tremor.
- **MS:** back pain, cramps, myalgia.
- **Misc:** infection, cushingoid appearance, flu-like syndrome.

**Interactions**

**Drug-Drug:**
- Known inhibitors of the CYP3A4 enzyme system including ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, and erythromycin; may ↓ levels; ↓ dose may be necessary.
- St. John's wort may ↑ levels.

**Drug-Food: **Grapefruit juice significantly ↑ blood levels; concurrent use should be avoided.

**Route/Dosage**

**Treatment of Active Crohn's Disease (Entocort EC)**

| PO (Adults): | 9 mg once daily in the morning for up to 8 wk; recurring episodes of active disease can be treated with a repeat 8-wk course of therapy. |

**Maintenance of Remission of Crohn's Disease (Entocort EC)**

| PO (Adults): | 6 mg once daily for up to 3 mos. If symptoms con- |

**Concomitant $\text{med} = $** concurrent use should be avoided.
Induction of Remission of Ulcerative Colitis (Uceris)

PO (Adults): 9 mg once daily in the morning for up to 8 wk.

NURSING IMPLICATIONS

Assessment
- Assess signs of Crohn’s disease and Ulcerative Colitis (diarrhea, crampy abdominal pain, fever, bleeding from rectum) during therapy. Monitor frequency and consistency of bowel movements periodically during therapy.
- Lab Test Considerations: May cause leukocytosis.

Potential Nursing Diagnoses

Diarrhea (Indications)

Implementation
- Periods of stress, such as surgery, may require supplemental systemic corticosteroids.
- Patients with mild to moderate Crohn’s disease may be switched from oral prednisolone without adrenal insufficiency by gradually decreasing prednisolone doses and adding budesonide.
- PO: Administer once daily in the morning. Capsules and extended-release tablets should be swallowed whole; do not open, crush, break or chew.
- Consumption of grapefruit juice should be avoided throughout therapy.

Patient/Family Teaching
- Instruct patient to take medication as directed. Do not share medication with others, even if they have similar symptoms; may be harmful.
- May cause dizziness. Caution patient to avoid driving or other activities requiring alertness until response to medication is known.
- Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and to consult health care professional before taking any Rx, OTC, or herbal products.
- Instruct patient to notify health care professional immediately if exposed to chicken pox or measles.
- Instruct patient to notify health care professional if they are planning or suspect pregnancy or if breast feeding or planning to breastfeed.

Evaluation/Desired Outcomes
- Improvement in symptoms includes of Crohn’s disease and ulcerative colitis (decreased frequency of liquid stools, decreased abdominal complaints, improved sense of well-being).

Why was this drug prescribed for your patient?