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IN THIS ISSUE

In Brief: Extended-Release Budesonide (*Ortikos*) for Crohn's Disease.....p 176

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IN BRIEF

Extended-Release Budesonide (*Ortikos*) for Crohn's Disease

An oral extended-release formulation of the corticosteroid budesonide (*Ortikos* – Ferring) is now available for once-daily treatment of mild to moderate active Crohn's disease of the ileum and/or ascending colon in patients ≥ 8 years old and for maintenance of remission for up to 3 months in adults. *Ortikos* is the second oral formulation of budesonide to be approved for this indication; *Entocort EC*, an ileal-release formulation, was the first.¹ A third oral formulation of budesonide (*Uceris*) is approved for induction of remission in patients with mild to moderate active ulcerative colitis.

Pronunciation Key

Ortikos: or tee' kos

Corticosteroids are effective for short-term symptom control and induction of remission in mild to moderate Crohn's disease. Budesonide is a synthetic corticosteroid with a strong affinity for glucocorticoid receptors and a high ratio of local anti-inflammatory to systemic effects.²

No new clinical trials were required for approval of *Ortikos*; approval was based on the results of earlier trials with *Entocort EC* in patients with mild to moderate Crohn's disease.

Table 1. Oral Budesonide for Crohn's Disease

Drug	Some Formulations	Usual Adult Dosage	Cost ¹
<i>Entocort EC</i> (Perrigo) generic	3 mg DR caps ^{2,3}	Induction: 9 mg PO once/day x 8 wks Maintenance: 6 mg PO once/day (max 3 months)	\$1380.90 285.90
<i>Ortikos</i> (Ferring)	6, 9 mg ER caps ²	PO once/day (max 3 months)	1200.00

DR = delayed-release; ER = extended-release

1. Approximate WAC for 30 days' maintenance treatment. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly, October 5, 2020. Reprinted with permission by First Databank, Inc. All rights reserved. ©2020. www.fdbhealth.com/policies/drug-pricing-policy.
2. Capsules should be swallowed whole, and not be crushed or chewed.
3. Capsules can be opened and contents sprinkled on one tablespoonful of applesauce and consumed immediately.

Oral budesonide is a substrate of CYP3A4; coadministration of CYP3A4 inhibitors including grapefruit juice could increase budesonide serum concentrations and possibly its toxicity.³

The only apparent advantage of *Ortikos* over *Entocort EC* is that patients can take one capsule rather than 2 or 3 capsules once daily. ■

1. Drugs for inflammatory bowel disease. Med Lett Drugs Ther 2018; 60:107.
2. GR Lichtenstein et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol 2018; 113:481.
3. Inhibitors and inducers of CYP enzymes and P-glycoprotein. Med Lett Drugs Ther 2020 September 10 (epub). Available at: medicalletter.org/downloads/CYP_PGP_Tables.pdf.

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