

Learning Objectives:

- Describe ulcerative colitis
- Briefly summarize current pharmacologic treatments for ulcerative colitis
- Discuss Uceris (budesonide multi-matrix extended release tablets)
- Review efficacy/safety trial of oral budesonide MMX and its place in treatment of ulcerative colitis

Intro:

Ulcerative colitis is mucosal inflammation of the colon characterized by bloody, frequent stools. It affects nearly 500,000 people in the U.S. with an incidence of 8-12 per 100,000 per year. Estimates put hospital costs and drug costs for ulcerative colitis at \$960 million annually and \$680 million annually, respectively. The inflammation is confined to the rectum and colon, often producing crypt abscesses in the mucosa and submucosa. Perinuclear antineutrophil cytoplasmic antibodies (pANCA) are usually present in UC. Depending on disease severity, treatment usually begins with a locally acting 5-aminosalicylic acid derivative with or without oral 5-ASA treatment. Patients who fail to respond to these treatments can use corticosteroids, immunosuppressants, or TNF alpha inhibitors.

Body:

Budesonide is a potent corticosteroid that undergoes extensive first pass metabolism. Entocort is a controlled ileal release budesonide shown to be effective for the treatment of active, mild to moderate Crohn's disease. MMX® technology allows for delayed, continuous release of budesonide in the colon. In a phase 3, multicenter, randomized, double-blind, double dummy, parallel group, placebo-controlled trial budesonide MMX extended release tablet treatment was analyzed for efficacy and safety in active, mild to moderate ulcerative colitis. Primary endpoint was combined clinical and endoscopic remission at week 8 with secondary endpoints of clinical remission, endoscopic remission, symptom resolution, and histologic healing. Study results showed a statistically significant benefit of budesonide MMX 9mg compared to placebo for clinical and endoscopic remission of active, mild to moderate ulcerative colitis as well as symptom resolution. (17.9% vs 7.4% P=0.0143 and 28.5% vs 16.5% P=0.0258)

Conclusion:

Uceris provides an ulcerative colitis therapy as a corticosteroid, but with very little systemic effects associated with prednisone. Being a new branded medication with a newer release mechanism, the cost of one month treatment is more than some other treatments already available. Uceris would be an appropriate choice of therapy in patients who have failed to achieve remission with 5-ASA derivatives and prednisone before use of immunosuppressants and/or TNF alpha inhibitors. More studies would be needed to determine efficacy in those situations as well as with concurrent 5-ASA use. Determination of Uceris' place as maintenance therapy needs to be studied as well.

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