

## Use of Budesonide in Eosinophilic Esophagitis

The goal of OPA's Drug Information Challenge is to highlight quality drug information responses solicited from students across the state, who submitted questions from physicians, educators, patients and preceptors. Submissions were encouraged to be innovative and unique. Judges scored responses on grammar, punctuation, completeness of response, strength of references, and clarity of recommendation.

This year's winner was Sarah Turley, PharmD candidate 2015 from Ohio Northern University. Her article, *Guaifenesin in Fertility*, was published in the April 2014 issue of the *Ohio Pharmacist*.

The following article, *Use of Budesonide in Eosinophilic Esophagitis*, was submitted by Abira Corrigan, PharmD candidate 2014 from The Ohio State University and received honorable mention.

### **Can budesonide (Pulmicort®) be used orally for the treatment of eosinophilic esophagitis, and how should it be administered?**

#### **Response:**

When other pharmacologic therapies and dietary modification are not an option, the off-label use of oral budesonide (Pulmicort®) for the treatment of eosinophilic esophagitis has been studied and used in clinical practice as an effective treatment option in pediatric and adult populations.<sup>1</sup> Studies support the use of oral budesonide for treatment aimed at resolving clinical symptoms, the maintenance of disease remission, improving quality of life, preventing fibrotic complications, and avoiding the use of medications (i.e. systemic steroids) with iatrogenic effects.

In the pediatric population, a retrospective analysis of 20 children showed oral budesonide treatment to be highly effective in achieving histological and clinical remission.<sup>2</sup> No significant adverse events were observed. A randomized, double-blind, placebo-controlled trial in 24 children showed a significantly higher response rate of improved histologic features with oral budesonide (n=15) when compared to placebo (n=9) ( 87% vs. 0%).<sup>3</sup> Again, no significant adverse events were reported.

A randomized, double-blind, placebo-controlled trial conducted in 36 adult and adolescent patients demonstrated similar results, with oral budesonide therapy resulting in rapid histologic and clinical remission.<sup>4</sup> In addition, patients receiving budesonide (n=18) had significant improvements in dysphagia when compared to placebo (n=18) (72% vs. 22%). The oral budesonide was reported to be well tolerated with no serious adverse events reported.

Budesonide dosing based on these trials is 1 mg daily for children less than ten years of age and 2 mg daily for children ten years of age and older and adults. To administer budesonide orally, a viscous budesonide formulation can be compounded according to the following:<sup>2-3</sup>

- Mix two or four (depending on desired dose) 0.5 mg/2 mL Pulmicort Respules® with sucralose (Splenda® or equivalent product).
- Use ten 1 gram packets of sucralose for each 1 mg of budesonide to create a volume of approximately 8 mL.
- It is recommended that patients do not eat or drink for 30 minutes following administration of the above formulation.

**Final recommendation:**

The off-label use of oral budesonide for the treatment of eosinophilic esophagitis can be used as a safe and effective treatment option in both the pediatric and adult populations. When systemic steroid therapy, dietary modification, and acid suppression are not desired or are ineffective a viscous budesonide formulation can be compounded, with 10 grams of sucralose for every 1 mg budesonide, for use in these situations to resolve clinical symptoms and maintain remission of the disease.<sup>1</sup>

**References**

1. Lucendo AJ, Molina-Infante J. Emerging therapeutic strategies for eosinophilic esophagitis. *Curr Treat Options Gastroenterol* 2014;12(1):1-17.
2. Aceves SS, Bastian JF, Newbury RO, et al. Oral viscous budesonide: a potential new therapy for eosinophilic esophagitis in children. *Am J Gastroenterol* 2007;102:2271-9.
3. Dohil R, Newbury R, Fox L, et al. Oral viscous budesonide is effective in children with eosinophilic esophagitis in a randomized, placebo-controlled trial. *Gastroenterology* 2010;139:418.
4. Straumann A, Conus S, Degen L, et al. Budesonide is effective in adolescent and adult patients with active eosinophilic esophagitis. *Gastroenterology* 2010;139:1526-37.