

The Mortar & Pestle:

MD Custom Rx's monthly e-newsletter

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MDCustomRx.com

Greetings!

Thank you for entrusting in the compounding services at MD Custom Rx to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to continuing to be your medication problem solvers. Please don't ever hesitate to let us know how we can be of further assistance to you and your practice.



Sincerely,
Dan, Monica and John

Oral Viscous Sucralfate Gel for Post-Procedural Treatment of Barrett's Esophagus & Other Problems Solved with Topical Sucralfate Preparations

Barrett's esophagus (BE) is an abnormal change in the cells of the lower portion of the esophagus, characterized by the replacement of the normal stratified squamous epithelium lining of the esophagus by columnar epithelium cells which are usually found lower in the gastrointestinal tract. Patients with BE have approximately an 0.5% risk of developing esophageal adenocarcinoma. In general, high-grade dysplasia and early stages of adenocarcinoma can be treated by endoscopic resection and/or endoscopic ablative therapy, whereas advanced stages (submucosal) generally require surgical treatment. Patients who undergo endoscopic resection and/or endoscopic ablative therapy might suffer from retrosternal discomfort and transient dysphagia, adverse effects that sometimes accompany these procedures. One of the common post-procedural treatments is oral sucralfate suspension or viscous gel, 1 gram four times

daily for two weeks after the procedure. The rationale for this treatment is to enhance the wound-healing process in the esophageal tissues and to coat the wounded tissues with sucralfate, a cytoprotective agent.

Population studies suggest that gastroesophageal reflux disease (GERD) is increasing in prevalence, both in the U.S. and worldwide. The diagnosis of GERD is associated with a 10% to 15% risk of BE. Other risk factors associated with the development of BE include:

- Long-standing GERD
- Male gender
- Obesity
- Age over 50 years

Thirteen peer-reviewed articles have described the use of 5 mL of sucralfate suspension (200 mg/mL) 4 times a day for a period of 2 weeks after each endoscopic treatment of BE to ease the retrosternal discomfort and transient dysphagia that accompanies this procedure.



Randomized clinical trials (RCTs) have shown the benefit of topical sucralfate therapy for the treatment of:

- chronic venous leg ulcers
- burn wounds
- chronic radiation-induced proctitis (A sucralfate enema was chosen as a first-line treatment for this pathology by the Mucositis Study Group of Multinational Association of Supportive Care in Cancer in collaboration with the International Society of Oral Oncology).

RCTs have shown the benefit of sucralfate preparations to enhance wound-healing following:

- Hemorrhoidectomy
- Fistulotomy
- Tonsillectomy

However, less success has been noted for oral mucositis, radiotherapy-induced skin tissue damage and radiotherapy-induced esophagitis.

[Pharmaceutics. 2018 Sep; 10\(3\): 159](#)

[Int J Pharm Compd. 2019 Sep-Oct;23\(5\):376-381.](#)

Oral Viscous Budesonide for Treatment of Eosinophilic Esophagitis

Eosinophilic esophagitis (EoE) has been increasingly recognized as a cause of food impactions and dysphagia. Short-term treatment goals include symptomatic and histological improvement, with prevention of fibrostenosis the primary long-term goal. Topical steroids are first-line treatment agents for EoE. In a study cohort of 75 EoE patients at Walter Reed National Military Medical Center, with a median age of 33 years (range 2-64 years), overall histologic response rate to topical steroids was 51%, while 71% improved clinically. Reed et al. of the Center for Esophageal Diseases and Swallowing, University of North Carolina School of Medicine noted that because no commercially available medications exist for treatment of EoE, patients must use off-label or compounded medications.

The efficacy of a compounded budesonide suspension was assessed in a retrospective cohort study of 48 EoE patients (mean age 33.6; 69% male). After a mean length of follow-up of 17 months, there was a significant decrease in symptoms of dysphagia (95% vs. 32%), improvements in heartburn (37% vs. 11%) and global symptom response (81%).

The median of the peak eosinophil counts decreased from 55 to 20 eos/hpf with 42% achieving a response of <15 eos/hpf. Esophageal candidiasis was rare (6%). In the 18 patients with prior non-response to corticosteroids or dietary elimination, 83% had symptomatic and 38% had histologic response. Compounded budesonide suspension produced a durable symptomatic, endoscopic, and histologic response in a cohort followed for more than a year. Many patients previously refractory to prior therapy responded to compounded budesonide.

Also at the University of North Carolina School of Medicine, a randomized clinical trial assessed whether oral viscous budesonide (OVB) was more effective than fluticasone MDI for initial treatment of patients with EoE. Patients with a new diagnosis of EoE were randomly assigned to groups given 8 weeks of either OVB (1 mg/4 mL) twice daily plus a placebo inhaler (n = 56) or fluticasone MDI (880 µg) twice daily plus a placebo slurry (n = 55). The subjects had baseline peak eosinophil counts of 73 and 77 eos/hpf in the OVB and MDI groups, respectively. Post-treatment eosinophil counts were 15 and 21 in the OVB and fluticasone MDI groups, respectively, with 71% and 64% achieving histologic response. Esophageal candidiasis developed in 12% of patients receiving OVB and 16% receiving fluticasone MDI; oral thrush was observed in 3% and 2%, respectively.

Aakash Goyal, MD, Assistant Professor in the Department of Pediatrics at UT Southwestern Medical Center, Dallas, who provides medical care at Children's Medical Center Dallas, found that oral viscous budesonide (OVB) which has muco-adhesive properties, has been more effective than a fluticasone inhaler in achieving remission of EoE.

Maintenance therapy at a reduced dosage is typically required because relapse is common after discontinuation of therapy.

[Dig Dis Sci. 2016 Jul;61\(7\):1996-2001.](#)

[Curr Opin Pediatr. 2018 Oct;30\(5\):646-652.](#)

[HSOA J Gastroenterol Hepatol Res. 2018;7\(1\):2509-2515.](#)

[Dig Dis Sci. 2019 Jun;64\(6\):1571-1578.](#)

[Gastroenterology. 2019 Jul;157\(1\):65-73.e5](#)

Mucoadhesive Formulations and Thermal Reversibility

Poloxamer 407-based hydrogels exhibit an interesting reversible thermal characteristic. That is, they are liquid at room temperature, but become a gel when warmed to body temperature, which makes them attractive candidates as pharmaceutical drug carriers. Poloxamer is an excellent choice for mucoadhesive formulations because it does not irritate the mucosal membranes. Based on its mucoadhesive properties, simple administration into a specific compartment should maintain the required drug concentration in situ for a prolonged period of time, decreasing the necessary dosages and side effects. Poloxamer 407 is also known by the trademark Pluronic® F127.

Poloxamer 407 gels have been shown to be compatible with various types of medications and active pharmaceutical ingredients (APIs). It can be administered via various routes, including:

- Orally to treat the esophagus
- Nasal
- Topical
- Rectal

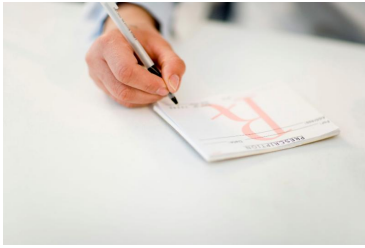
[Pharmaceutics. 2018 Sep; 10\(3\): 159](#)

[Int J Pharm Compd. 2019 Sep-Oct;23\(5\):380-381.](#)

If your patient may benefit from a mucoadhesive preparation such as viscous sucralfate or budesonide, call our compounding pharmacist to discuss the therapeutic options.

MD Custom Rx Educational Events

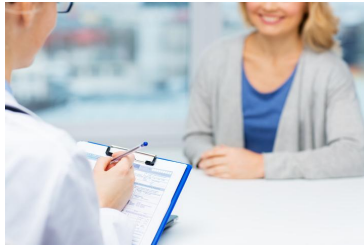
We regularly offer educational events at the pharmacy. Be sure to share our events with your patients. **VISIT OUR WEBSITE** to see our schedule and to register. If you are interested in speaking on a topic, please contact the pharmacy.



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At MD Custom Rx, we strive to provide the best quality of care. Your comments are important to us and they will help us to continue to improve the services we provide.

[Please take a moment to review us.](#)

