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Efficacy of a Next Generation Low Volume Bowel Prep

Announcer: This is ReachMD. Welcome to this medical industry feature, titled “Efficacy of a Next Generation Low Volume Bowel Prep,” sponsored by Ferring Pharmaceuticals Inc. This program is intended for Physicians. Here’s your host, Dr. Sophie Balzora.

Dr. Balzora: There’s a lot to consider when it comes to selecting bowel preparations for your patients. Efficacy, safety and tolerability are most likely at the top of your list. Despite improvements in the palatability of bowel preparations, challenges remain, and many screenings are either aborted or are suboptimal for effective screening as a result of inadequate preparation process. In this podcast, we will consider the potential therapeutic and patient value of a recently introduced low volume prep and is ready-to-drink.

This is ReachMD, and I’m Dr. Sophie Balzora. Joining me to talk about a next-generation low-volume, ready-to-drink bowel prep is Dr. Lawrence Hookey, Medical Director for Endoscopy at Hotel Dieu and Kingston general hospitals. Dr. Hookey, welcome to the program.

Dr. Hookey: Thanks so much for having me.

Dr. Balzora: So, let’s just dive right in here, Dr. Hookey. Tell us why you consider CLENPIQ (sodium picosulfate, magnesium oxide and anyhydrous citric acid) oral solution to be a next generation low-volume prep?

Dr. Hookey: Calling it a next generation low-volume prep is reasonable because it’s the only FDA approved ready-to-drink bowel prep, that requires no mixing or diluting.

Dr. Balzora: Now let's take some time to focus on the recent publication you were the lead author in regarding new clinical trial data for CLENPIQ, “Efficacy and safety of a ready-to-drink bowel preparation for colonoscopy: a randomized, controlled, non-inferiority trial” first published on May 19, 2019. What were the major efficacy findings in this head-to-head study?

Dr. Hookey: So, before we even get into the findings, we need to understand how we came to this study. The safety and efficacy of CLENPIQ was based on clinical trials of another powder formulation of sodium picosulfate, magnesium oxide, and anhydrous citric acid. On the basis of these studies the product was established as being non-inferior to a 2L PEG+E plus two 5 mg bisacodyl tablets. In the split-dose regimen trial supporting FDA approval, 84% of patients achieved excellent or good[1,2*] visualization of the overall colon, which is using the Aronchick scale, where scoring of the colon occurs before washing and suctioning.

For the key secondary endpoint, 90% of patients achieved successful cleansing of the ascending colon, defined as "excellent", "good", or "fair"[2*] using the Ottawa scale. Most common side effects, were nausea 3%, headache 2%, and vomiting 1%.

We now have recently published CLENPIQ specific data based on a randomized, assessor-blinded, multicenter, non-inferiority study comparing split-dose, low volume CLENPIQ oral solution against an oral powder for reconstitution.

The study included a large sample size of 901 participants; the randomized, controlled trial design; multicenter study with several types of participating sites; efficacy was measured using 2 validated scales that measure colon cleansing on colonoscopy insertion and withdrawal. Also, the assessments were performed by a treatment-blinded endoscopist. The primary efficacy endpoint assessed overall colon cleansing quality with the Aronchick Scale which scores the colon cleanse prior to washing or suctioning, and the key secondary efficacy endpoint rated quality of right colon cleansing with the Boston Bowel Preparation Scale. The Boston scale’s score is reflective of the colon cleanse after you do your washing and suctioning of fluid at the time of withdrawal.

Split-dose CLENPIQ efficacy on the primary endpoint included 88% of patients achieving excellent or good overall colon cleansing as assessed by the Aronchick scale. Additionally, the secondary endpoints showed that 94% of patients achieved cleansing in the right colon, 96% in the transverse, and 95% in the left colon segments, as assessed by the Boston bowel prep scale. When you take a look

at the mean total score on Boston bowel prep scale CLENPIQ scored a 7.7.[3]

Dr. Balzora: Thanks for breaking all of that down for us, Dr. Hookey. And just as a follow-up to that, what were the most commonly reported adverse events in this study?

Dr. Hookey: CLENPIQ was well tolerated. 3% of participants taking CLENPIQ reported nausea, 3% headache, and 2% hypermagnesemia. Hypermagnesemia levels were transient and not associated with any clinical significant sequelae. In the CLENPIQ arm, 8 of the 9 patients with reported hypermagnesemia returned to baseline within 24 to 48 hours. One patient returned to baseline by their day 7 follow-up visit. It's also important to note that only 1% of patients reported vomiting as an adverse event.

Dr. Balzora: One last question, how did patients in this recently published study rate their experience with CLENPIQ?

Dr. Hookey: Patient compliance and tolerability were evaluated using the Mayo Clinic Bowel Prep Tolerability questionnaire. In our study, 99%, or almost all patients, who took CLENPIQ reported that they were able to complete the prep and only 2/447 (0.4%) had at least 25% of the bowel preparation left. The ability to complete the bowel prep is an important consideration in selecting a bowel prep, along with the efficacy and safety profile of the prep. CLENPIQ performed very well on all key parameters in this study and could be a suitable bowel prep for most adult patients undergoing a colonoscopy screening.

Dr. Balzora: Well I think that says it all, and with that, I want to thank you Dr. Hookey for joining me to discuss the Efficacy of a Next Generation Low Volume Prep for our ReachMD audience.

Dr. Hookey: My pleasure. I love talking about our research.

Announcer: For those listening, CLENPIQ indication for use and important safety information below

**Indication**

CLENPIQ oral solution is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

**Important Safety Information**

CLENPIQ is contraindicated in the following conditions: patients with severe renal impairment (creatinine clearance less than 30mL/minute), gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, or in patients with a known hypersensitivity to any of the ingredients in CLENPIQ.

Patients should be advised to hydrate adequately (before, during and after use of CLENPIQ), and post-colonoscopy lab tests should be considered if a patient develops significant vomiting or signs of dehydration, including orthostatic hypotension, after taking CLENPIQ. Patients with electrolyte abnormalities should have them corrected before treatment. Use caution when prescribing CLENPIQ for patients that have conditions or are using medications that increase the risk for fluid and electrolyte abnormalities.

Use caution in patients who have conditions, or are taking concomitant medications that increase the risk for seizures, such as those taking medications that lower the seizure threshold, patients withdrawing from alcohol or benzodiazepines or patients with known or suspected hyponatremia.

Use caution in patients with impaired renal function or taking medications that may affect renal function, as well as patients at increased risk of arrhythmias, including those patients with a history of prolonged QT, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy.

Osmotic laxatives may produce colonic mucosal aphthous ulcerations and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of additional stimulant laxatives with CLENPIQ may increase this risk.

Use caution in patients with severe active ulcerative colitis.

Use caution in patients with impaired gag reflex as they may be at risk for regurgitation or aspiration during administration of CLENPIQ.

The safety of CLENPIQ has been established from adequate well controlled trials of another oral formulation of sodium picosulfate, magnesium oxide and anhydrous citric acid. The most common adverse reactions in those trials were nausea, headache, and vomiting.

CLENPIQ can reduce the absorption of co-administered drugs. Do not take oral medications within one hour of starting CLENPIQ. Administer tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine, at least 2 hours before and not less than 6 hours after administration of CLENPIQ to avoid chelation with magnesium.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call 800.FDA.1088.

To see the full prescribing information, visit CLENPIQ.com.

Announcer: The preceding program was sponsored by Ferring Pharmaceuticals Inc. To listen to other programs in this series, please visit ReachMD.com/NextGenBowelPrep. This is ReachMD. Be Part of the Knowledge.

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