Clenpiq™ (sodium picosulfate/magnesium oxide/anhydrous citric acid) – New drug approval

- On November 29, 2017, Ferring announced the FDA approval of Clenpiq (sodium picosulfate/magnesium oxide/anhydrous citric acid) for cleansing of the colon as a preparation for colonoscopy in adults.

- Clenpiq is a ready-to-drink oral solution containing sodium picosulfate, a stimulant laxative, and magnesium oxide and anhydrous citric acid, which form magnesium citrate, an osmotic laxative.

    — Sodium picosulfate/magnesium oxide/anhydrous citric acid is also available as Prepopik®, a powder formulation that must be reconstituted with cold water before use. Prepopik has the same indication as Clenpiq.

- The approval of Clenpiq was based on data from two non-inferiority studies of 1,195 patients randomized to another oral formulation of sodium picosulfate/magnesium oxide/anhydrous citric acid or a polyethylene glycol plus electrolyte solution in combination with bisacodyl tablets.

    — In study 1, sodium picosulfate/magnesium oxide/anhydrous citric acid was given by "Split-Dose" dosing. In study 2, sodium picosulfate/magnesium oxide/anhydrous citric acid was given by "Day-Before" dosing.
    — In both studies, the sodium picosulfate/magnesium oxide/anhydrous citric acid combination demonstrated non-inferiority vs. the comparator in the proportion of patients achieving successful colon cleansing.
    — Sodium picosulfate/magnesium oxide/anhydrous citric acid provided by the Split-Dose regimen met the pre-specified criteria for superiority to the comparator for colon cleansing in study 1. The comparator in that study was administered entirely on the day prior to colonoscopy.

- Clenpiq is contraindicated in patients with severe renal impairment, gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, and in patients with hypersensitivity to any of the ingredients in Clenpiq.

- Warnings and precautions of Clenpiq include serious fluid and serum chemistry abnormalities; seizures; use in patients with renal impairment; cardiac arrhythmias; colonic mucosal ulceration, ischemic colitis, and ulcerative colitis; use in patients with significant gastrointestinal disease; and aspiration.

- The most common adverse reactions (> 1%) with Clenpiq use were nausea, headache, and vomiting.

- Clenpiq is ready to drink and does not need to be diluted prior to administration. Two doses (two bottles) of Clenpiq are required for a complete preparation for colonoscopy either as a "Split-Dose" (preferred) or "Day-Before" dosing regimen.

    — The "Split-Dose" method consists of two separate doses: the first dose during the evening before the colonoscopy and the second dose the next day, approximately 5 hours prior to the colonoscopy.
    — The "Day-Before" method consists of two separate doses: the first dose during the afternoon or early evening before the colonoscopy and the second dose approximately 6 hours later during the evening before the colonoscopy.
    — Additional fluids must be consumed after every dose of Clenpiq in both dosing regimens.
    — Refer to the Clenpiq drug label for further administration details.

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- Ferring plans to launch Clenpiq oral solution in the first quarter of 2018. Clenpiq will be available as a carton of two bottles, each containing 10 mg of sodium picosulfate, 3.5 g of magnesium oxide, and 12 g of anhydrous citric acid in 160 mL of solution.