Suflave® (polyethylene glycol 3350/sodium sulfate/potassium chloride/ magnesium sulfate/sodium chloride) – New drug approval

- On June 15, 2023, the FDA approved Braintree Laboratories' Suflave (polyethylene glycol 3350/sodium sulfate/potassium chloride/magnesium sulfate/sodium chloride), for cleansing of the colon in preparation for colonoscopy in adults.

- The efficacy of Suflave was established in two randomized, single-blind, active-controlled trials in adult patients undergoing colonoscopy. In Study 1, 471 adult patients were included in the efficacy analysis. Patients were randomized to one of the following two colon preparation regimens: Suflave or polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate for oral solution. In Study 2, 450 adult patients were included in the efficacy analysis. Patients were randomized to one of the following two colon preparation regimens: Suflave or sodium sulfate, potassium sulfate, and magnesium sulfate oral solution. The primary endpoint in each study was the proportion of patients with successful colon cleansing, utilizing a four-point scale.

    - In both studies, Suflave was non-inferior to the active comparator.
    - In Study 1, successful colon cleansing was achieved in 93% of patients with Suflave vs. 89% with the active comparator (treatment difference 3.4, 95% CI: -1.7, 8.5).
    - In Study 2, successful colon cleansing was achieved in 94% of patients treated with Suflave or active comparator (treatment difference 0.2, 95% CI: -4.0, 4.3).

- Suflave is contraindicated in the following conditions:

    - Gastrointestinal obstruction or ileus
    - Bowel perforation
    - Toxic colitis or toxic megacolon
    - Gastric retention
    - Hypersensitivity to any ingredient in Suflave.

- Warnings and precautions for Suflave include serious fluid and electrolyte abnormalities; cardiac arrhythmias; seizures; use in patients with risk of renal injury; colonic mucosal ulcerations and ischemic colitis; use in patients with significant gastrointestinal disease; aspiration; and hypersensitivity reactions.

- The most common adverse reactions (≥ 2%) with Suflave use were nausea, abdominal distension, vomiting, abdominal pain, and headache.

- The recommended split-dose (two-day) regimen of Suflave consists of two doses:

    - Day 1, dose 1: evening before colonoscopy: 1 bottle with flavor enhancing packet
    - Day 2, dose 2: morning of the colonoscopy (5 to 8 hours prior to the colonoscopy and no sooner than 4 hours from starting dose 1): 1 bottle with flavor enhancing packet.

- Refer to the Suflave drug label for complete dosing and administration recommendations.

- Braintree Laboratories' launch plans for Suflave are pending. Suflave will be available as two bottles and two flavor enhancing packets.

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- Each bottle contains 178.7 g polyethylene glycol 3350, 7.3 g sodium sulfate, 1.12 g potassium chloride, 0.9 g magnesium sulfate, and 0.5 g sodium chloride. The bottle also contains lemon-lime flavoring.