Emend® (aprepitant) oral suspension – New Formulation

- On December 17, 2015, the FDA announced the approval of Merck’s Emend (aprepitant) oral suspension, in combination with other antiemetic agents, in patients ≥ 6 months of age for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
  - Previously, Emend was only available as capsules and as an injection.
  - Emend has not been studied for the treatment of established nausea and vomiting.
  - Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.
- The safety and efficacy of Emend oral suspension were based on data from a double-blind study involving 302 pediatric patients 6 months – 17 years of age receiving HEC or MEC. Patients received Emend in combination with ondansetron (Emend group) or ondansetron alone (control group) for the prevention of chemotherapy induced nausea and vomiting (CINV). The primary endpoint was complete response (no vomiting or retching and no use of rescue medication) in the delayed phase (25 – 120 hours following initiation of chemotherapy).
  - The data showed that 50.7% of patients in the Emend group vs. 26% of patients in the control group achieved complete response in the delayed phase (p < 0.01).
- Warnings and precautions of Emend include clinically significant CYP3A4 drug interactions, decrease in international normalized ratio (INR) with concomitant warfarin, and risk of reduced efficacy of hormonal contraceptives.
- Emend is contraindicated with concurrent use of pimozide.
  - Inhibition of CYP3A4 by Emend could result in elevated plasma concentrations of pimozide, which is a CYP3A4 substrate, potentially causing serious or life-threatening reactions, such as QT prolongation, a known adverse reaction of pimozide.
- For the prevention of CINV in pediatrics, the most common adverse events (≥ 3%) with Emend use were neutropenia, headache, diarrhea, decreased appetite, cough, fatigue, decreased hemoglobin, dizziness, and hiccups.
- For the prevention of CINV in adults, the most common adverse events (≥ 3%) with Emend use were fatigue, diarrhea, asthenia, dyspepsia, abdominal pain, hiccups, decreased white blood cell count, dehydration, and increased alanine aminotransferase.
- For CINV in pediatric patients 6 months to < 12 years of age or patients unable to swallow capsules, the recommended dose of Emend oral suspension is 3 mg/kg (maximum 125 mg) on day 1 and 2 mg/kg (maximum 80 mg) on days 2 and 3.
  - Dosing in pediatric patients < 6 kg is not recommended.

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For patients ≥ 12 years of age who cannot swallow oral capsules, Emend oral suspension can be used instead of Emend capsules.

- Merck’s launch plans for Emend oral suspension are pending. Emend oral suspension will be available as a 125 mg pink powder in a single-use pouch with dispensers and a mixing cup.