

Emend[™] (fosaprepitant) – Expanded indication

- On April 3, 2018, the <u>FDA announced</u> the approval of Merck's <u>Emend (fosaprepitant dimeglumine)</u> for injection in pediatric patients 6 months of age and older in combination with other antiemetic agents for the prevention of:
 - Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
 - Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- Previously, Emend for injection was approved for the above indications in adults only.
 - Emend (aprepitant) for oral suspension is approved for adults and pediatric patients 6
 months of age and older for the same HEC indication as well as nausea and vomiting
 associated with initial and repeat courses of MEC.
 - Emend oral capsules is indicated for patients 12 years of age and older for the same indications as the oral suspension formulation, with an added indication for prevention of postoperative nausea and vomiting in adults.
- The safety and effectiveness of a single-dose regimen of Emend for injection and a 3-day Emend regimen is supported by evidence from studies in adults with additional safety, efficacy, and pharmacokinetic data in pediatric patients 6 months to 17 years.
- Adverse reactions with Emend injection use in pediatrics are similar to adults, and include fatigue, diarrhea, neutropenia, asthenia, anemia, peripheral neuropathy, leukopenia, dyspepsia, urinary tract infection, and pain in extremity.
- The recommended dose of Emend injection for pediatric patients is dependent upon chemotherapy regimen duration and the patient's age and weight.
 - For use with single-day chemotherapy regimens in patients 12 to 17 years of age, the
 recommended dose of Emend injection is 150 mg IV through a central venous catheter over
 30 minutes either as a single dose or followed by orally administered Emend as part of a 3
 day regimen.
 - For use with multi-day chemotherapy regimens in patients 12 to 17 years of age, the recommended dose of Emend injection is 115 mg IV through a central venous catheter over 30 minutes followed by orally administered Emend as part of a 3 day regimen.
 - Younger patients should be dosed based on the patient's weight and require a longer infusion time.
 - Refer to the Emend drug label for dosages of concomitant antiemetics, weight based dosing recommendations, and adult dose recommendations.



optumrx.com

Optum Rx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

 $All \ Optum^{@} trademarks \ and \ logos \ are \ owned \ by \ Optum, \ Inc. \ All \ other \ brand \ or \ product \ names \ are \ trademarks \ or \ registered \ marks \ of \ their \ respective \ owners.$

 $This document \, contains information \, that \, is considered \, proprietary \, to \, Optum \, Rx \, and \, should \, not \, be \, reproduced \, without \, the \, express \, written \, consent \, of \, Optum \, Rx.$

RxNews[®] is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.