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Hematology/Oncology, Pharmacology, FDA Update

FDA Update: New regimen helps prevent nausea, vomiting in children receiving chemotherapy

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health and Division of Gastroenterology and Inborn Errors Products

Emend (aprepitant) has been approved by the Food and Drug Administration for use with other antiemetic agents to prevent chemotherapy-induced nausea and vomiting (CINV) in pediatric patients.

Aprepitant (Merck Sharp & Dohme Corp.) is the first neurokinin 1 receptor antagonist approved for U.S. children.

The medication is used to prevent CINV for up to 120 hours after initiation of chemotherapy in patients ages 6 months to 17 years. An oral solution is approved for use in patients 6 months and older. A capsule is approved for use in patients 12 years and older. Aprepitant is administered as part of a combination antiemetic regimen that includes a 5HT-3 antagonist and dexamethasone.

The medication was studied in 302 pediatric patients receiving chemotherapy who took aprepitant in combination with ondansetron or ondansetron alone. The pediatric trial was completed pursuant to the Pediatric Research Equity Act, which requires drug companies to study their products in children under certain circumstances.

Because of the unique mechanism of action, the addition of aprepitant to 5-HT3 antagonists and corticosteroids is a valuable new option for prevention of CINV in children.

The safety and effectiveness of aprepitant have not been established for the prevention of postoperative nausea and vomiting in pediatric patients.

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