

Prescribing Information _ **MFL0030-00**

A copy of the currently approved US product labeling is provided. During the reporting period from 05-Jun-2022 to 04-Sep-2022, the following changes were made in the Reference product (*Emend*) PI for Fosaprepitant for Injection USP.

Section Number	Revision Type	Revision
6 ADVERSE REACTIONS	Addition (underlined)	<p>6.1 Clinical Trials Experience: In pediatric patients 6 months to 12 years of age, the safety of the 3-day IV/oral/oral EMEND regimen was not directly evaluated. The safety of a single dose of EMEND for injection (3 mg/kg) administered on day 1 of the 3-day IV/oral/oral regimen was evaluated in one active-controlled and one single-arm study including 48 <u>pediatric patients 6 months to 12 years of age</u> who received a regimen of either HEC or MEC.</p> <p><u>The safety of the 3-day (IV/IV/IV) regimen of EMEND for injection in pediatric patients (6 months to 17 years) was evaluated in a single-arm clinical study in 100 patients who received either HEC or MEC.</u></p> <p><u>In these clinical studies, pediatric patients also received ondansetron with or without dexamethasone. The adverse reaction profile in pediatric patients was similar to the profile in adult patients receiving a single dose of EMEND for injection.</u></p>
8 USE IN SPECIFIC POPULATIONS	Addition	<p>8.4 Pediatric Use: <u>The safety of the 3-day EMEND for injection regimen in pediatric patients 6 months to 17 years of age was supported by an open-label study in 100 patients receiving HEC or MEC.</u> See the full prescribing information for EMEND capsules for complete clinical information regarding studies performed with oral aprepitant. Adverse reactions were similar to those reported in adult patients.</p>
17 PATIENT COUNSELING INFORMATION	Addition	<p>PATIENT INFORMATION</p> <p>How will I receive EMEND for injection?</p> <p>Children 6 months to 17 years of age: EMEND for injection will be given to your child by intravenous (IV) infusion into a large vein through a type of IV line called a central venous catheter, about 1 hour to 1 ½ hours before the start of their chemotherapy treatment.</p> <p>Depending on the chemotherapy treatment, <u>there are 2 ways that EMEND for injection may be given:</u></p> <p><u>EMEND for injection is given on Day 1 only (single day of chemotherapy).</u></p>

Section Number	Revision Type	Revision
		<p data-bbox="748 232 1458 300"><u>EMEND for injection is given on Days 1, 2, and 3 (single or multiple days of chemotherapy).</u></p> <p data-bbox="748 338 1458 546">Your child may receive capsules of EMEND or an oral suspension of EMEND <u>instead of EMEND for injection</u> on Days 2 and 3. If your child will receive either of these, see the Patient Information for EMEND capsules or EMEND for oral suspension for further information.</p>

MSN Comment: MSN will update its US PI to be in-line with reference product.