EMVOID I.V.

For the use only of an Oncologist only

Abbreviated Prescribing information for EMVOID I.V. [Fosaprepitant Dimeglumine for Injection] [Please refer the complete prescribing information available at www.torrentpharma.com] PHARMACOLOGICAL PROPERTIES: Fosaprepitant dimeglumine is a substance P/neurokinin-1 (NK1) receptor antagonist. Fosaprepitant is a prodrug of aprepitant and accordingly, its antiemetic effects are attributable to aprepitant. INDICATION: Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults. Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults. DOSAGE AND ADMINISTRATION: Fosaprepitant for Injection 150 mg (Single Dose Regimen). Fosaprepitant for Injection 150 mg is administered intravenously on Day 1 only as an infusion over 20-30 minutes initiated approximately 30 minutes prior to chemotherapy. Fosaprepitant 150 mg injection should be used for Single Dose Regimen only. CONTRAINDICATION: It is contraindicated in patients who are hypersensitive to Fosaprepitant for Injection, aprepitant or any other components of the product. Concomitant use with pimozide or cisapride is also contraindicated. WARNINGS & PRECAUTIONS: Fosaprepitant should be used with caution in patients receiving concomitant medications that are primarily metabolized through CYP3A4. Co-administration of it with warfarin may result in a clinically significant decrease in International Normalized Ratio (INR) of prothrombin time. It may decrease the efficacy of hormonal contraceptives. Its chronic continuous use is not recommended. DRUG INTERACTIONS: It is a moderate inhibitor and an inducer of CYP3A4 when administered as a 3-day antiemetic dosing regimen for chemotherapy-induced nausea and vomiting. Aprepitant is also an inducer of CYP2C9. It may interact with CYP3A4 substrates and also with 5-HT3 antagonists, corticosteroids (dexamethasone, methylprednisolone), chemotherapeutic agents like docetaxel, oral contraceptives, midazolam, CYP2C9 substrates (warfarin, tolbutamide), ketoconazole, rifampin and paroxetine. ADVERSE REACTIONS: Hiccups, fatigue, ALT increased, AST increased, constipation, dyspepsia, diarrhea, headache, anorexia, pruritus, rash, urticaria, rarely Stevens-Johnson syndrome/toxic epidermal necrolysis, hypersensitivity reactions including anaphylactic reactions.

MARKETED BY:



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(Additional information is available on request)