

EMVOID

For the use of an Oncologist or a Hospital or a Laboratory only.

Abbreviated Prescribing information for EMVOID (Combipack of Aprepitant Capsules 125 mg and 80 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Aprepitant is a selective high-affinity antagonist of human substance P/neurokinin 1 (NK1) receptors. Aprepitant has been shown in animal models to inhibit emesis induced by cytotoxic chemotherapeutic agents, such as cisplatin, via central actions. Animal and human studies show that aprepitant augments the antiemetic activity of the 5-HT₃-receptor antagonist ondansetron and the corticosteroid dexamethasone and inhibits both the acute and delayed phases of cisplatin-induced emesis. **INDICATIONS:** For the prevention of chemotherapy induced nausea and vomiting in adult patients. **DOSAGE AND ADMINISTRATION:** Aprepitant is given for 3 days as part of a regimen that includes a corticosteroid and a 5-HT₃ antagonist. The recommended dose of aprepitant is 125 mg orally 1 hour prior to chemotherapy treatment (Day 1) and 80 mg orally once daily in the morning on Days 2 and 3. It may be taken with or without food. **CONTRAINDICATIONS:** EMVOID is contraindicated in patients who are hypersensitive to any component of the product. Aprepitant should not be used concurrently with pimozone, terfenadine, astemizole, or cisapride. Inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions. **WARNINGS AND PRECAUTIONS:** Coadministration with Warfarin: decrease in International Normalized Ratio (INR) of prothrombin time. Coadministration with Hormonal Contraceptives: the efficacy of hormonal contraceptives may be reduced. Caution should be exercised when aprepitant is administered in Patients with Severe Hepatic Impairment. Chronic continuous use of aprepitant is not recommended because it has not been studied; and because the drug interaction profile may change during chronic continuous use. **DRUG INTERACTIONS:** Effect of Aprepitant on the Pharmacokinetics of Other Agents: CYP3A4 substrates, 5-HT₃ antagonist, Corticosteroids, Chemotherapeutic agents, CYP2C9 substrates (Warfarin, Tolbutamide), Oral contraceptives, Midazolam. Effect of Other Agents on the Pharmacokinetics of Aprepitant: rifampin, carbamazepine, phenytoin, Ketoconazole. Additional Interactions: Diltiazem, Paroxetine. **ADVERSE REACTIONS:** Asthenia, Fatigue, Nausea, Constipation, Diarrhea, Anorexia, Hiccups, Headache, Alopecia, pruritus, rash, urticarial, rarely Stevens-Johnson syndrome/toxic epidermal necrolysis, hypersensitivity reactions including anaphylactic reactions, ifosfamide-induced neurotoxicity.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ EMVOID 125, 80 mg /JUN-2016/01/ABPI

(Additional information is available on request)