Emestop™

Aprepitant Capsule

Presentation
Emestop™ Capsule: Each capsule contains Aprepitant INN 40 mg.
Emestop™ 125 Capsule: Each capsule contains Aprepitant INN 125 mg.

Description
Aprepitant is a selective high affinity antagonist of human substance P neurokinin 1 (NK1) receptors. When substance P attaches to these receptors, it causes nausea and vomiting. Aprepitant stops substance P from binding to the NK1 receptors. By blocking the receptors, Aprepitant can prevent nausea and vomiting, which often happens after chemotherapy or as a complication of surgery.

Indications and usage
Emestop is indicated for-
- Prevention of postoperative nausea and vomiting (PONV)
- Prevention of Chemotherapy Induced Nausea and Vomiting (CINV)

Dosage and administration

Post Operative Nausea and Vomiting
The recommended oral dosage of Emestop is 40 mg within 3 hours prior to induction of anesthesia.
Chemotherapy Induced Nausea and Vomiting
The following regimen should be used for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy:

	Day 1	Day 2	Day 3	Day 4
Emestop*	125 mg orally	80 mg orally	80 mg orally	none
Dexamethasone**	12 mg orally	8 mg orally	8 mg orally	8 mg orally
5-HT3 antagonist (Ondansetron)	24 mg 30 minutes before the start of chemotherapy.	none	none	none

*Emestop is administered orally 1 hour prior to chemotherapy treatment on Day 1 and in the morning on Days 2 and 3. **Dexamethasone is administered 30 minutes prior to chemotherapy treatment on Day 1 and in the morning on Days 2 through 4. The dose of dexamethasone accounts for drug interactions.

The following regimen should be used for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy:

	Day 1	Day 2	Day 3
Emestop*	125 mg orally	80 mg orally	80 mg orally
Dexamethasone**	12 mg orally	none	none
5-HT3 antagonist (Ondansetron)	One 8 mg tablet 30 minutes before chemotherapy followed by an 8 mg dose 8 hours later.	8 mg tablet twice a day	8 mg tablet twice a day

*Emestop is administered orally 1 hour prior to chemotherapy treatment on Day 1 and in the morning on Days 2 and 3. **Dexamethasone is administered 30 minutes prior to chemotherapy treatment on Day 1. The dose of dexamethasone accounts for drug interactions.

Emestop may be taken with or without food. No dosage adjustment is necessary for the elderly patients.

Patients with Renal Impairment- No dosage adjustment is necessary for patients with renal impairment or for patients with end stage renal disease (ESRD) undergoing hemodialysis.
Patients with Hepatic Impairment- No dosage adjustment is necessary for patients with mild to moderate hepatic impairment. There are no clinical data in patients with severe hepatic impairment .

Side effects
● Constipation ● Hypotension ● Pruritus ● Pyrexia

Contraindication
Aprepitant is contraindicated in patients who are hypersensitive to any component of the product. Aprepitant should not be used concurrently with Pimozide, Terfenadine, Astemizole & Cisapride.

Use in pregnancy and lactation
Pregnancy Category B: This drug should be used during pregnancy only if clearly needed.
It is not known whether this drug is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug based on patient's importance.

Drug interaction
Aprepitant is a substrate, a weak-to-moderate (dose-dependent) inhibitor, and an inducer of CYP3A4. Aprepitant is also an inducer of CYP2C9. Precautions should be taken while coadministering Aprepitant with drugs that use CYP3A4 or CYP2C9, for example.-Warfarin, Tolbutamide, Phenytoin, Ketoconazole, Itraconazole, Nefazodone, Troleandomycin, Clarithromycin, Ritonavir, Nelfinavir, Diltiazem, Rifampin, Carbamazepine etc.
Upon coadministration with Aprepitant, the efficacy of hormonal contraceptives during and for 28 days following the last dose of Aprepitant may be reduced. Alternative or back-up methods of contraception should be used during treatment with Aprepitant and for 1 month following the last dose of Aprepitant.

Overdose
No specific information is available on the treatment of overdosage with Aprepitant. Single doses up to 600 mg of Aprepitant were generally well tolerated in healthy subjects. Drowsiness and headache can be seen due to overdose. In the event of overdose, Aprepitant should be discontinued. General supportive treatment and monitoring should be provided. Because of the antiemetic activity of Aprepitant, medicine-induced emesis may not be effective. Aprepitant cannot be removed by hemodialysis.

Commercial pack
Emestop™ capsule: Each box contains 1 alu-alu blister strip of 4 capsules.
Emestop™ 125 capsule: Each box contains 1 alu-alu blister strip of 4 capsules.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

V.N.02

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