Apridex-40
Capsule

DRUG INTERNATIONAL LTD.

Composition : Each Capsule Contains Aprepitant USP 40mg.

Pharmacology : 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 : Apridex 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 Apridex 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
Apridex*	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	

*Apridex 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
Apridex*	125 mg orally	80 mg orally	8 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 hours later.	80 mg tablet twice a day	80 mg tablet twice a day

*Apridex 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. Apridex 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. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients known to have hypersensitivity to aprepitant or any other components of this product.

Precautions : Co administration of Aprepitant with Warfarin (aCYP2C9 substrate) may result in a clinically significant decrease in International Normalized Ratio (INR) of prothrombin time. The efficacy of hormonal contraceptives during and for 28 days following the last dose of Aprepitant may be reduced. Caution should be exercised when administered in patients with severe hepatic impairment.

Side effects : Constipation, Hypotension, Pruritus and Pyrexia.

Drug interactions : 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.

Use in pregnancy and lactation : Pregnancy: Pregnancy Category B. There are no adequate and well controlled studies in pregnant women. Aprepitant should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human milk.

Overdose : No specific information is available on the treatment of overdosage with Aprepitant. Single doses up tö 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.

Storage : Store below 30° C in a dry place.

Packing : Each box contains 1 x 5's capsules in blister pack.