

Composition : Palnox 0.5 tablet : Each Film Coated Tablet Contains Palonosetron 0.5mg as Palonosetron Hydrochloride USP.

Pharmacology : Nausea and Vomiting is usually produced by chemotherapeutic agents by releasing serotonin from the enterochromaffin cells of the small intestine. The released serotonin (5-HT) then activates 5-HT₃ receptors located on vagal afferents to initiate the vomiting reflex. Palonosetron is a 5-HT₃ receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors. So by binding with this receptor palonosetron inhibits binding of serotonin to this receptor and also inhibits vomiting reflux.

Indications : Moderately emetogenic cancer chemotherapy : prevention of acute and delayed nausea and vomiting associated with initial and repeat courses.

Highly emetogenic cancer chemotherapy : prevention of acute nausea and vomiting associated with initial and repeat courses.

Prevention of post operative nausea and vomiting for up to 24 hours following surgery. Efficacy beyond 24 hours has not been demonstrated.

Dosage and administration :
Chemotherapy-Induced Nausea and Vomiting (Dosage for Adults) Tablet : 0.5 mg tablet approximately 1 hour before the start of chemotherapy.

Post operative Nausea and Vomiting (Dosage for Adults) : In case of 0.5 mg tablet, dose should be determined by the physician. Or, as directed by the registered physicians.

Contraindication : Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components.

Precautions : Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT₃ receptor antagonists.

Palnox-0.5
Tablet



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LTD.**

Side effects : Most commonly reported adverse effects are- headache, constipation, abdominal pain, fatigue, dizziness, insomnia.

Use in Pregnancy and lactation :

Pregnancy : Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Therefore, Palonosetron should be used during pregnancy only if clearly needed. **Nursing mothers :** It is not known whether Palonosetron is excreted in human milk. So caution should be exercised when this tablet is administered to a nursing woman.

Use in Child : Safety and effectiveness of Palonosetron in pediatric patients under 18 years of age have not been established.

Drug Interactions : In vitro studies indicated that palonosetron is not an inhibitor of CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2D6, CYP2E1 and CYP3A4/5 (CYP2C19 was not investigated) nor does it induce the activity of CYP1A2, CYP2D6, or CYP3A4/5. Therefore, the potential for clinically significant drug interactions with palonosetron appears to be low.

Overdose : There is no known antidote to palonosetron. Overdose should be managed with supportive care.

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

Packing : Palnox 0.5 tablet : Each box contains 3 x 14's tablets in blister pack.