

Palosis®

Palonosetron Hydrochloride INN Tablet and Capsule

DESCRIPTION

Palosis® is a preparation of Palonosetron. Palonosetron is a 5-HT₃ receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors. Cancer chemotherapy may be associated with a high incidence of nausea and vomiting, particularly when certain agents, such as Cisplatin, are used. 5HT₃ receptors are located on the nerve terminals of the vagus in the periphery and centrally in the chemoreceptor trigger zone of the area postrema. It is thought that chemotherapeutic agents produce nausea and vomiting by releasing serotonin from the enterochromaffin cells of the small intestine and that the released serotonin then activates 5-HT₃ receptors located on vagal afferents to initiate the vomiting reflex.

INDICATIONS

Palosis® is indicated in adults for:

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

DOSAGE AND ADMINISTRATION

► Dosage for Adult:

One 0.5 mg Tablet or Capsule administered approximately one hour prior to the start of Chemotherapy.

Palosis® can be taken with or without food.

CONTRAINDICATIONS

Palosis® is contraindicated in patients known to have hypersensitivity to the drug.

SIDE EFFECTS

- Headache
- Constipation

WARNING AND PRECAUTION

Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT₃ receptor antagonists. Serotonin syndrome has been reported with 5-HT₃ receptor antagonists alone but particularly

USE IN PREGNANCY AND LACTATION

Pregnancy Category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Palonosetron should be used during pregnancy only if clearly needed. It is not known whether Palonosetron is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants and the potential for tumorigenicity shown for Palonosetron in the rat carcinogenicity study, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of the children.

PACKAGING

Palosis® Tablet: Box containing 2 strips of 10 tablet each. Each tablet contains Palonosetron Hydrochloride INN equivalent to Palonosetron 0.5 mg.

Palosis® Capsule: Box containing 4 strips of 5 capsules each. Each capsule contains Palonosetron Hydrochloride INN equivalent to Palonosetron 0.5 mg.

SK•F

Manufactured by


ESKAYEF BANGLADESH LIMITED.

TONGI, GAZIPUR, BANGLADESH

@REGD. TRADEMARK

PM04318 V01

PM Specification

Job Name	Palosis Insert	Paper	: 60 gsm offset paper
Size	: L - 70 mm, W - 125 cm	Lamination	: N/A
Print	: 1 Color	Loading Process	: N/A
Pantone Code:	 PANTONE 2735 C	Others	:

CSD 04 UZL

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- ▶ Headache
- ▶ Constipation

WARNING AND PRECAUTION

Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other 5-HT₃ receptor antagonists. Serotonin syndrome has been reported with 5-HT₃ receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

USE IN PREGNANCY AND LACTATION

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PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of the children. Tablet should be stored below 30 °C temperature.

PACKAGING

Palosis® Capsule: Box containing 4 strips of 5 capsules each. Each capsule contains Palonosetron Hydrochloride INN equivalent to Palonosetron 0.5 mg.

Palosis® Tablet: Box containing 2 strips of 10 tablets each. Each film coated tablet contains Palonosetron Hydrochloride INN equivalent to Palonosetron 0.5 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED.

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