Naurif®

Granisetron

COMPOSITION

Naurif® Injection: Each 1 ml injection ampoule contains Granisetron 1 mg as Granisetron Hydrochloride BP.
Naurif® Tablet: Each tablet contains Granisetron 1 mg as Granisetron Hydrochloride BP.

PHARMACOLOGY

Granisetron is a selective 5-hydroxytryptamine 3 (5-HT_3) receptor antagonist with no affinity for other serotonin receptors, including 5-HT_1; 5-HT_1A; 5-HT_1B/C; 5-HT_2; 5-HT_4 for α_1, α_2, or ß adrenoceptors; dopamine (D_2); histamine (H_1); benzodiazepine; picrotoxin or opioid receptors.

INDICATION AND USE

Naurif® ***(Granisetron) Injection is indicated for:*** The prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, therapy including high dose cisplatin. The prevention and treatment of postoperative nausea and vomiting.
Naurif® ***(Granisetron) Tablet is indicated for:*** Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high dose of cisplatin. Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

DOSAGE AND ADMINISTRATION

Naurif® *(Granisetron) Injection:*

CHEMOTHERAPY INDUCED NAUSEA AND VOMITING

Adults: The recommended dosage for **Naurif®** Injection is 10mcg/kg administered intravenously within 30 minutes before initiation of chemotherapy and only on the day(s) chemotherapy is given. **Naurif®** Injection may be administered intravenously either undiluted over 30 seconds or diluted with 0.9% Sodium Chloride or 5% Dextrose and infused over 5 minutes. As a general precaution, **Naurif®** Injection should not be mixed in solution with other drugs.
Paediatric Patients: The recommended dose in paediatric patients 2 to 16 years of age is 10mcg/kg. Paediatric patients under 2 years of age have not been studied.
Geriatric Patients, Renal Failure Patients or Hepatically Impaired Patients: No dosage adjustment is required.

TREATMENT OF POSTOPERATIVE NAUSEA AND VOMITING

Adults: The recommended dosage for prevention of postoperative nausea and vomiting is, a single dose of 1 mg of **Naurif®** should be diluted to 5 ml and administered as a slow intravenous injection (over 30 seconds). Administration should be completed prior to induction of anesthesia. The recommended dosage for the treatment of nausea and vomiting after surgery is 1 mg of **Naurif®** undiluted, administered intravenously over 30 seconds.
Paediatric Patients: Safety and effectiveness of **Naurif®** Injection have not been established in paediatric patients for the prevention or treatment of postoperative nausea or vomiting.
Geriatric patients, Renal Failure Patients or Hepatically Impaired Patients: No dosage adjustment is required.

Naurif® ***(Granisetron) Tablet:*** Emetogenic chemotherapy: The recommended adult dosage of oral Granisetron is 2 mg once daily or 1 mg twice daily. In the 2 mg once-daily regimen, two 1 mg tablets are given up to one hour before chemotherapy. In the 1 mg twice-daily regimen, the first 1 mg tablet is given up to one hour before chemotherapy, and the second tablet, 12 hours after the first. Either regimen is administered only on the days(s) chemotherapy is given. Use in the Elderly, Renal Failure Patients or Hepatically Impaired Patients: No dosage adjustment is required. Radiation (either total body irradiation or fractionated abdominal radiation): The recommended adult dosage of oral Granisetron is 2 mg once daily. Two 1 mg tablets are taken within one hour of irradiation. Paediatric use: There is no experience with oral Granisetron in the prevention of radiation induced nausea and vomiting in paediatric patients.

CONTRAINDICATION

Granisetron is contraindicated in patients with known hypersensitivity to Granisetron or any of its components.

SIDE-EFFECTS

Headache, constipation, asthenia, diarrhea, abdominal pain, dyspepsia, nausea and vomiting, dizziness, insomnia, anxiety.

DRUG INTERACTION

Granisetron does not induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system. As Granisetron is metabolized by hepatic cytochrome P-450 drug metabolizing enzymes, inducers or inhibitors of these enzymes may change the clearance and the half-life of granisetron.

PREGNANCY: Pregnancy category B. No evidence of impaired fertility or harm to the animal fetus have been found. However, this drug may be used in pregnancy only if clearly needed.

NURSING MOTHER: It is not known whether Granisetron is excreted in human milk. So caution should be exercised when granisetron is administered to a nursing mother.

PAEDIATRIC USE: Safety and effectiveness of granisetron in paediatric patients under 2 years have not been established.

GERIATRIC USE: Efficacy and safety were maintained with increasing age.

STORAGE

Naurif® Injection. Store below 25°C. Protect from light.
Naurif® Tablet: Store below 30°C. Protect from light.

HOW SUPPLIED

Naurif® Injection: Each box contains 1 x 5's injection in blister pack.
Naurif® Tablet: Each box contains 2 x 10's tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH