Onamis

Ondansetron

COMPOSITION:
Onamis Tablet: Each film coated tablet contains 8 mg of Ondansetron as Ondansetron Hydrochloride Dihydrate BP.
Onamis Oral Solution: Each 5 ml solution contains 4 mg of Ondansetron as Ondansetron Hydrochloride Dihydrate BP.

DESCRIPTIONS:
Ondansetron is a selective 5-HT3 receptor antagonist. While its mechanism of action has not been fully characterized, Ondansetron is not a dopamine-receptor antagonist. Serotonin receptors of the 5-HT3 type are present both peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. It is not certain whether Ondansetron's antiemetic action is mediated centrally, peripherally, or in both sites. However, cytotoxic chemotherapy appears to be associated with release of serotonin from the enterochromaffin cells of the small intestine.

INDICATIONS:
- Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy.
- Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
- Prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
- Prevention of postoperative nausea and/or vomiting.
- Nausea-vomiting associated with pregnancy
- Nausea-vomiting associated with gastroenteritis

DOSAGE & ADMINISTRATION:
1. Prevention of nausea-vomiting associated with chemotherapy
- Adult

Oral: Highly emetogenic cancer chemotherapy: 24 mg (three 8 mg tablet) administered 30 minutes before start of emetogenic chemotherapy
Moderate emetogenic cancer chemotherapy: 8 mg (one 8 mg tablet) administered 30 minutes before start of emetogenic chemotherapy. A further 8 mg dose should be administered after 8 hours of the first dose. One 8 mg tablet should be administered twice a day (every 12 hours) for 1-2 days after completion of chemotherapy.
- Pediatric

Oral (4-11 years): 4 mg tablet should be taken 30 minutes before the start of chemotherapy. The other 2 doses should be taken 4 and 8 hours after the first dose. Then 4 mg tablet should be administered 3 times a day (every 8 hours) for 1-2 days after completion of chemotherapy.
2. Prevention of nausea-vomiting associated with radiotherapy
Adults/ Geriatric/ Child of 12 years or over
The recommended dose is 8 mg tablet 3 times a day.
For total body irradiation: One 8 mg tablet should be administered 1 to 2 hours before each fraction of radiotherapy administered each day.
For single high-dose fraction radiotherapy to the abdomen: One 8 mg tablet should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy.
For daily fractionated radiotherapy to the abdomen: One 8 mg tablet should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day.
3. Prevention of post-operative nausea-vomiting
- Adults/ Geriatric/ Child of 12 years or over

Oral: 16 mg (two 8 mg tablets) 1 hour before induction of anesthesia.
- Pediatric (1 months to12 years)

4. Nausea-vomiting in gastroenteritis
- Adult: 8 mg three times daily.
- Pediatric (1 month or over): 0.15 mg/kg body weight three times daily.

5. Nausea vomiting in pregnancy
8 mg (1 tablet) 2-3 times daily

SIDE EFFECTS:
Generally Ondansetron is well tolerated. However few side effects including headache, diarrhoea, fatigue, dizziness and constipation may be seen after Ondansetron is administered.

PRECAUTIONS:
Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction. The use of Ondansetron in patients following abdominal surgery or in patients with chemotherapy-induced nausea and vomiting may mask a progressive ileus and/or gastric distension.

CONTRAINDICATIONS:
Ondansetron is contraindicated for patients known to have hypersensitivity to the drug.

USE IN PREGNANCY & LACTATION:
Pregnancy: Pregnancy category B.
Nursing mother: It is not known whether Ondansetron is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ondansetron is administered to a nursing woman.

DRUG INTERACTION:
The following drugs should be used with caution when concomitantly used with Ondansetron: Phenytoin, Carbamazepine, Rifampicin & Tramadol.

OVERDOSE:
There is no specific antidote for Ondansetron overdose. Hypotension (and faintness) occurred in a patient that took 48 mg of Ondansetron tablets.

STORAGE CONDITION:
Store in a cool and dry place, protected from light and moisture.

PACKAGING:
Onamis Tablet: Each Box contains 3X10's tablets in Alu-PVC blister packs.
Onamis Oral Solution: Each bottle contains 50 ml solution with a measuring cup.

Apex™
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Manufactured by
Apex Pharma Limited
Shafipur, Kaliakair, Gazipur, Bangladesh