Dantron

Ondansetron

Composition

Dantron Tablet: Each film coated tablet contains Ondansetron Hydrochloride Dihydrate USP 9.977 mg equivalent to Ondansetron 8 mg.

Dantron Syrup: Each 5 ml syrup contains Ondansetron Hydrochloride Dihydrate BP equivalent to Ondansetron 4 mg.

Pharmacology

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.

Indication

1. Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including Cisplatin ≥ 50 mg/m2
2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy
3. 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
4. Prevention of post-operative nausea and/or vomiting
5. Nausea-vomiting associated with pregnancy
6. Nausea-vomiting associated with gastroenteritis

Dose and Administration

Route of administration: Oral

Tablet

Chemotherapy-Induced Nausea and Vomiting-

Adults, Pediatric patients (6 months to 18 years):

8 mg tablet: Three 0.15 mg/kg doses, up to a maximum of 16 mg per dose.

Radiotherapy-Induced Nausea and Vomiting-

Adults:

8 mg tablet: Initial Dose: 8 mg orally 1 to 2 hours before radiotherapy.

Post Radiotherapy: 8 mg orally every 8 hours for up to 5 days after a course of treatment.

Postoperative Nausea and Vomiting-

Adults:

8 mg tablet: 16 mg given as two 8 mg tablets

Syrup

Chemotherapy-induced Nausea and Vomiting-

Adults/Geriatric/Child of 12 years or over:

Highly emetogenic cancer chemotherapy: 30 ml (24 mg) Ondansetron Oral Solution administered 30 minutes before start of emetogenic chemotherapy.

Moderate emetogenic cancer chemotherapy: 10 ml (8 mg) Ondansetron Oral Solution administered 30 minutes before start of emetogenic chemotherapy. A further 10 ml dose should be administered after 8 hours of the first dose. One 10 ml dose should be administered twice a day (every 12 hours) for 1-2 days after completion of chemotherapy.

Pediatric (4-11 years): 5 ml (4 mg) Ondansetron Oral Solution 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 5 ml oral solution should be administered 3 times a day (every 8 hours) for 1-2 days after completion of chemotherapy.

Radiotherapy induced Nausea and Vomiting-

Adults/Geriatric/Child of 12 years or over:

The recommended oral dosage: 10 ml (8 mg) Ondansetron Oral Solution 3 times daily.

For total body irradiation: 10 ml (8-mg) Ondansetron Oral Solution 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 10 ml Ondansetron Oral Solution 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: 10 ml (8-mg) Ondansetron Oral Solution should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day radiotherapy is given.

Postoperative Nausea and Vomiting-

Adults/Geriatric/Child of 12 years or over: 20 ml (16 mg) Ondansetron Oral Solution 1 hour before induction of anesthesia.

Contraindication

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

Warning and Precaution

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.

Side-effects

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

Rare: Blurred vision or vision loss, rash, hives, hoarseness, difficulty breathing or swallowing, chest pain, shortness of breath, dizziness, light-headedness, or fainting, slow or irregular heartbeat, agitation, hallucinations (seeing things or hearing voices that do not exist), fever, excessive sweating, confusion, loss of coordination, stiff or twitching muscles, seizures, coma (loss of consciousness) etc.

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.

Use in Children & Adolescents

Should be used as per direction of physician.

Drug Interaction

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

With food and others: Grapefruit juice.

Overdose

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

Storage

Store below 30° C temperature and cool and dry place, away from light. Keep out of the reach of children.

Packing

Dantron Tablet: Each box contains 3 blister of 10 tablets.

Dantron Syrup: Each bottle contains 50 ml Syrup.

Manufactured by
ONE PHARMA LTD.
C-23-24, BSCIC I/A
Bogura, Bangladesh

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