Onaseron®

Ondansetron

473

473

Presentation

Onaseron• ODT tablet: Each tablet contains Ondansetron USP 4 mg.
Onaseron• tablet: Each film coated tablet contains Ondansetron Hydrochloride Dihydrate USP 9.977 mg equivalent to Ondansetron 8 mg.
Onaseron• 4 ml IV/IM injection: Each 4 ml contains Ondansetron Hydrochloride USP 9.977 mg equivalent to Ondansetron 8 mg.
Onaseron• oral solution: Each 5 ml contains Ondansetron Hydrochloride Dihydrate USP equivalent to Ondansetron 4 mg.

Description

Ondansetron is a selective 5-HT_3 receptor antagonist. While its mechanism of action has not been fully characterized, Ondansetron is not a dopamine-receptor antagonist. Serotonin receptors of the 5-HT_3 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 and Uses

1. Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including Cisplatin > 50 mg/m^2
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

Dosage and Administration

Onaseron ODT should be removed from the blister gently. Then it should be immediately placed on top of the tongue where it will dissolve in seconds and swallowed with saliva. Administration with liquid is not necessary.

Prevention of nausea-vomiting associated with chemotherapy:

Age category	Parenteral	ODT/Oral tablet	Oral solution
Adults/ Geriatric/ Child of 12 years or over	32 mg single dose infused over 15 minutes by diluting with 50 ml saline (5% dextrose or 0.9% NaCl) 30 minutes before starting chemotherapy. Alternative therapy Three dose of 0.15 mg/kg body weight. The first dose is infused over 15 minutes beginning 30 minutes before the starting chemotherapy. Subsequent doses (0.15 mg/kg) are administered 4 and 8 hours after the first dose of administration.	Highly emetogenic cancer chemotherapy: 24 mg administered 30 minutes before start of emetogenic chemotherapy Moderate emetogenic cancer chemotherapy: 8 mg administered 30 minutes before start of emetogenic chemotherapy. A further 8 mg dose should be administered after 8 hours of the first dose. 8 mg should be administered twice a day (every 12 hours) for 1-2 days after completion of chemotherapy.	Highly emetogenic cancer chemotherapy: 30 ml (24 mg) oral solution administered 30 minutes before start of emetogenic chemotherapy Moderate emetogenic cancer chemotherapy: 10 ml (8 mg) oral solution 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	6 months onwards: Three dose of 0.15 mg/kg body weight. The first dose is infused over 15 minutes beginning 30 minutes before starting moderately to highly emetogenic chemotherapy. Subsequent doses (0.15 mg/kg) are administered 4 and 8 hours after the first dose of administration.	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.	4-11 years: 5 ml (4 mg) 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 (4 mg) oral solution should be administered 3 times a day (every 8 hours) for 1-2 days after completion of chemotherapy.

Prevention of nausea-vomiting associated with radiotherapy

(Either Total Body Irradiation, or Single High-Dose Fraction or Daily Fractions to the Abdomen):

Age category	ODT/Oral tablet	Oral solution
Adults/ Geriatric/ Child of 12 years or over	The recommended dose is 8 mg 3 times a day. For total body irradiation: 8 mg should be administered 1 to 2 hours before each fraction of radiotherapy administered each day. For single high-dose fraction radiotherapy to the abdomen: 8 mg 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: 8 mg should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day.	The recommended dose is 10 ml (8 mg) oral solution 3 times a day. For total body irradiation: 10 ml (8 mg) 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: 10 ml (8 mg) 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) oral solution should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day.

Prevention of post-operative nausea-vomiting:

Parenteral	ODT/Oral tablet	Oral solution
Adults/ Geriatric/ Child of 12 years or over Undiluted 4 mg intravenously or intramuscularly immediately before induction of anesthesia. The rate of administration should not be less than 30 seconds, preferably over 2 to 5 minutes. Alternatively, the dose can be administered post-operatively if the patient experiences nausea and/or vomiting shortly after surgery. Pediatric (1 months to12 years) Weighing less than 40 kg: 0.1 mg/kg body weight in a Single dose. Weighing more than 40 kg: 4 mg single dose. The dose should be immediately before induction of anesthesia. The rate of administration should not be less than 30 seconds, preferably over 2 to 5 minutes. Alternatively, the dose can be administered post-operatively if the patient experiences nausea and/or vomiting shortly after surgery.	Adults/ Geriatric/ Child of 12 years or over 16 mg 1 hour before induction of anesthesia.	Adults/ Geriatric/ Child of 12 years or over 20 ml (16 mg) oral solution 1 hour before induction of anesthesia.

Contraindications

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

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.

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.

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 Interactions

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

Overdosage

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

Storage

Do not store above 30 ^{o}C. Keep away from light and out of the reach of children.

Commercial Pack

Onaseron• ODT tablet: Each box contains 3 blister strips of 10 tablets.
Onaseron• tablet: Each box contains 3 blister strips of 10 tablets.
Onaseron• 4 ml IV/IM injection: Each box contains 5 ampoules of 4 ml.
Onaseron• oral solution: Each bottle contains 50 ml oral solution.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
® Registered Trademark

ONS

V.N.01