W=100 mm

Periset

Film-Coated Tablet & Injection

Ondansetron Hydrochloride USP

DESCRIPTION

Ondansetron is a highly selective 5-HT_3 receptor antagonist. 5-HT_3 serotonin receptors are present both peripherally on vagal nerve terminals and centrally in chemoreceptor trigger zone of the 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 the release of serotonin from enterochromaffin cells of the small intestine.

COMPOSITION

Periset 8 mg Tablet: Each film-coated tablet contains Ondansetron Hydrochloride USP equivalent to Ondansetron 8 mg.
Periset 4 ml Injection: Each ml contains Ondansetron Hydrochloride USP equivalent to Ondansetron 2 mg.

INDICATIONS AND USES

- The prevention and treatment of Post-operative nausea and vomiting.
- The management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.

DOSAGE AND ADMINISTRATION

Prevention of nausea-vomiting associated with chemotherapy

Age Category	Oral tablet	Parentral (IM/IV)
Adults/ Geriatric/Child of 12 years or over	*Highly emetogenic cancer chemotherapy:* 24 mg (three 8 mg tablets) administrated 30 minutes before the start of emetogenic chemotherapy. *Moderate emetogenic cancer chemotherapy:* 8 mg (one 8 mg tablet) administrated 30 minutes before start of emetogenic chemotherapy. A further 8 mg dose should be administrated after 8 hours of the first dose. One 8 mg tablet should be administrated twice a day (every 12 hours) for 1-2 days after completion of chemotherapy.	32 mg single dose infused over 15 minutes by diluting with 50 ml saline (5% Dextrose or 9% NaCl) 30 minutes before starting chemotherapy. **Alternative therapy:** Three dose 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.
Pediatric	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.	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.

Prevention of nausea-vomiting associated with radiotherapy

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

Age Category	Oral tablet
Adults/ Geriatric/Child of 12 years or over	The recommended dose is 8 mg tablet thrice a day. For total body irradiation: one 8 mg tablet should be administered 1 to 2 hours before each fraction of radiotherapy administrated each day. For single high-dose fraction radiotherapy to the abdomen: one 8 mg tablet should be administrated 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 administrated 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

Age Category	Oral tablet	Parentral (IM/IV)
Adults/ Geriatric/Child of 12 years or over	16 mg (two 8 mg tablets) 1 hour before induction of anesthesia.	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 month to 12 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.

OR AS DIRECTED BY THE PHYSICIAN.

SIDE EFFECTS

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

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.

USE IN PREGNANCY & LACTATION

Pregnancy: Pregnancy category B.
Nursing mother: It is not known whether Ondansetron is excreted in human milk. So, caution should be exercised when Ondansetron is administered to nursing women.

DRUG INTERACTIONS

There is no evidence that Ondansetron either induces or inhibits the metabolism of other drugs commonly coadministered with it. But Ondansetron (HCl) is known to interact with other drugs like Carbamazepine, Phenytoin, Rifampicin and Tramadol.

OVERDOSAGE

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

Supply

Periset 8 mg Tablet: Each box contains 3 x 10 tablets in blister strips.
Periset 4 ml Injection: Each box contains 1 x 5 ampoules in blister strip.

Store in a cool & dry place, protected from light.
Keep all medicines out of reach of children.

**** Further information is available on request.***

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness