Emeren®

Ondansetron Hydrochloride USP

Tablet
Injection
Syrup

Presentation

Emeren® 4 Tablet : Each tablet contains Ondansetron Hydrochloride USP equivalent to Ondansetron 4mg.

Emeren® 8 Tablet : Each tablet contains Ondansetron Hydrochloride USP equivalent to Ondansetron 8mg.

Emeren® IM/IV Injection : Each 4mL injection contains Ondansetron Hydrochloride USP equivalent to Ondansetron 8mg.

Emeren® Syrup : Each 5mL syrup of 50mL syrup contains Ondansetron Hydrochloride BP equivalent to Ondansetron 4mg.

Description

Ondansetron (**Emeren®**) is a potent, highly selective 5-hydroxytryptamine-3 (5-HT_3) receptor antagonist with antiemetic activity. The effect of Ondansetron in the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of 5-HT_3 receptors on nervous system. The mechanism of action in postoperative nausea and vomiting are not known but there may be common pathways with cytotoxic induced nausea and vomiting.

Pharmacokinetics

Ondansetron (**Emeren®**) is well absorbed from the gastrointestinal tract and undergoes some first-pass metabolism. Mean bioavailability in healthy subjects is approximately 56% and bioavailability is also slightly enhanced by the presence of food and at higher doses but unaffected by antacids.

Indications

- Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including Cisplatin≥50mg/m2.
- Prevention of nausea & 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 and vomiting associated with pregnancy.
- Nausea and vomiting associated with gastroenteritis.

Dosage & Administration

Prevention of nausea & vomiting associated with chemotherapy

Age category	Parenteral	Oral tablet	Syrup
Child of 12 years or over/ Adult/Geriatric	32mg (four **Emeren®** injection) single dose infused over 15 minutes by diluting with 50mL saline (5% dextrose or 0.9% NaCl) before 30 minutes of starting of chemotherapy. **Alternative therapy:** 3 doses of 0.15mg/kg body weight. The first dose is infused over 15 minutes before 30 minutes of starting of chemotherapy. Subsequent doses of 0.15mg/kg body weight are administered 4 and 8 hours after first dose of administration.	**Highly emetogenic cancer chemotherapy:** 24mg (three 8mg tablets) should be administered before 30 minutes of starting of emetogenic chemotherapy. **Moderate emetogenic cancer chemotherapy:** 8mg (one 8mg tablet) should be administered before 30 minutes of starting of emetogenic chemotherapy. A further one 8mg tablet should be taken after 8 hours of the first dose. Then, one 8mg tablet should be taken twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.	**Highly emetogenic cancer chemotherapy:** 30mL (24mg) syrup should be taken before 30 minutes of starting of emetogenic chemotherapy. **Moderate emetogenic cancer chemotherapy:** 10mL (8mg) syrup should be taken before 30 minutes of starting of emetogenic chemotherapy. A further 10mL syrup should be taken after 8 hours of the first dose. Then, 10mL syrup should be taken twice a day (every 12 hours) for 1-2 days after completion of chemotherapy.
Pediatric	**6 months onwards:** 3 doses of 0.15mg/kg body weight. The first dose is infused over 15 minutes before 30 minutes of starting of moderate to highly emetogenic chemotherapy. Subsequent doses of 0.15mg/kg body weight are administered 4 and 8 hours after first dose of administration.	**4-11 years:** 4mg tablet should be taken before 30 minutes of starting of chemotherapy. The other 2 doses of 4mg tablet should be taken 4 and 8 hours after the first dose. Then 4mg tablet should be administered 3 times a day (every 8 hours) for 1-2 days after completion of chemotherapy.	**4-11 years:** 5mL (4mg) syrup should be taken before 30 minutes of starting of chemotherapy. The other 2 doses of 5mL syrup should be taken 4 and 8 hours after the first dose. 5mL syrup 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	Oral tablet	Syrup
Child of 12 years or over/ Adult/Geriatric	The recommended dose is 8mg tablet 3 times a day. For total body irradiation: one 8mg tablet should be administered before 1 to 2 hours of each fraction of radiotherapy. For single high dose fraction radiotherapy to the abdomen: one 8mg tablet should be administered before 1 to 2 hours of radiotherapy, with subsequent doses of 8mg tablet every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy. For daily fractioned radiotherapy to the abdomen: One 8mg tablet should be administered 1 to 2 hours before radiotherapy, with subsequent doses of 8mg tablet every 8 hours after the first dose of each day.	The recommended dose is 10mL syrup (8mg) 3 times a day. For total body irradiation: 10mL (8mg) syrup should be taken before 1 to 2 hours of each fraction of radiotherapy. For single high dose fraction radiotherapy to the abdomen: 10mL (8mg) syrup should be taken before 1 to 2 hours of radiotherapy, with subsequent doses of 10mL syrup every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy. For daily fractioned radiotherapy to the abdomen: 10mL (8mg) syrup should be taken 1 to 2 hours before radiotherapy, with subsequent doses of 8mg tablet every 8 hours after the first dose of each day.

Prevention of postoperative nausea & vomiting

Age category	Parenteral	Oral tablet	Syrup
Child of 12 years or over/ Adult/Geriatric	Undiluted 4mg 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.	16mg (two 8mg tablets) before 1 hour of induction of anesthesia.	20mL (16mg) syrup before 1 hour of induction of anesthesia.
Pediatric (1month to 12 years)	Weighing less than 40kg: 0.1mg/kg body weight in a single dose. Weighing more than 40kg: 4mg single dose. The dose should be administered 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 postoperatively if the patient experiences nausea and/or vomiting shortly after surgery.		

Contraindications

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

Side effects

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

Use in pregnancy & lactation

Pregnancy: The 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.

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.

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 48mg of Ondansetron tablets.

Storage

Store in a cool and dry place, away from light and children.

Packaging

Emeren® 4 Tablet: Each box contains 3x10 tablets in alu-alu blisters.

Emeren® 8 Tablet: Each box contains 3x10 tablets in alu-alu blisters.

Emeren® IM/IV Injection: Each box contains 1x5 ampoules in blister strip.

Emeren® Syrup: Each glass bottle contains 50mL syrup.

Manufactured by
RENATA LIMITED
Mirpur, Dhaka, Bangladesh