Only for the use of Medical Professionals

Osetron®

Ondansetron hydrochloride

Description

Osetron® is a selective 5-HT_3 serotonin receptor antagonist. 5-HT_3 serotonin receptors are present both peripherally on vagal nerve terminals and centrally in chemoreceptor trigger zone. During chemotherapy and postoperative period; excessive serotonin secrets from the enterochromaffin cells of the small intestine. The released serotonin stimulates the 5-HT_3 serotonin receptors of the vagal nerve terminals and chemoreceptor trigger zone which initiate vomiting reflex. Ondansetron is indicated for the prevention of chemotherapy & radiotherapy induced nausea and vomiting. It also prevents the postoperative nausea and vomiting.

Indications

Osetron® (tablets, syrup, and injection) is indicated for the prevention and treatment of nausea and vomiting induced by cytotoxic therapy and radiotherapy, postoperative nausea & vomiting.

Osetron® (injection) is indicated for nausea & vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high dose cilastin. **Osetron®** injection also indicated for the prevention and treatment of post-operative nausea and vomiting.

Dosage and administration

The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used.

Adults:

For emetogenic chemotherapy and radiotherapy (injection, tablets, and syrup): For the control of chemotherapy or radiotherapy induced emesis or nausea & vomiting in adults, a single dose of **Osetron®**8 mg injection should be administered by slow intravenously, immediately before treatment.

Alternatively, **Osetron®** 8 mg tablets or 10ml (2 teaspoonfuls equivalent to 8 mg of (Ondansetron) **Osetron®** syrup given twice a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with a subsequent dose 8 hours after the first dose.

To protect against delayed emesis after the first 24 hours, one **Osetron®** 8 mg tablet or 10 ml (2 teaspoonfuls equivalent to 8 mg of Ondansetron) of **Osetron®** oral solution should be administered twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

For highly emetogenic chemotherapy (injection, tablets, and syrup): A single dose of **Osetron®** 8 mg injection should be administered by slow intravenous infusion over at least 15 minutes, immediately before treatment.

Higher doses may be required in some patients, particularly those on high dose cisplatin, and the doses should be adjusted according to the severity of the emetogenic challenge. If required, additional intravenous doses may be given up to a maximum of 32 mg in 24 hours.

To protect against delayed emesis after initial treatment one **Osetron®** 8 mg tablet or 10 ml (2 teaspoonfuls equivalent to 8 mg of Ondansetron) of **Osetron®** oral solution should be administered twice a day (every 12 hours) for up to 5 days .
For prevention and treatment of post-operative nausea and vomiting (injection only): **Osetron®** 4 mg injection should be administered as a single dose, given by intramuscular or slow intravenous injection. If necessary, the dose may be increased up to 8 mg.

Children (12 years of age and older): The dosage of **Osetron®** is the same as for adults.

Children (over 4 years of age): For emetogenic chemotherapy and radiotherapy (injection, tablets, and oral solution): For the control of emetogenic chemotherapy or radiotherapy induced emesis or nausea & vomiting in children, a single dose of **Osetron®** (0.15 mg/kg) injection is to be administered 15 minutes before the start of emetogenic chemotherapy or radiotherapy, followed by oral therapy at doses of 4 mg tablet or 5ml (1 teaspoonful) of oral solution 2 times a daily or 1 to 2 days after completion of chemotherapy.

Or, **Osetron®** 4mg tablet or 5ml (1 teaspoonful) **Osetron®** oral solution of is given 3 times a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with a subsequent dose 4 and 8 hours after the first dose. To protect against delayed emesis after the first 24 hours, **Osetron®** 4 mg tablet or 5 ml (1 teaspoonful) **Osetron®** oral solution should be administered 3 times a day (every 8 hours) for 1 to 2 days after completion of chemotherapy.

Children only for injection (1 month to 12 years of age): For prevention and treatment of post-operative nausea and vomiting in children having surgery under general anaesthesia, **Osetron®** should be administered by slow intravenous injection at a dose of 0.1 mg/kg up to a maximum of 4 mg. The rate of administration should not be less than 30 seconds, preferably over 2 to 5 minutes immediately prior to or following anesthesia induction, or postoperatively if the patient experiences nausea and/or vomiting occurring shortly after surgery.

Preparation of solution before administration

Indication	**Dilution procedure**
Prevention of chemotherapy-induced nausea and vomiting	**Osetron®** I.V. Injection should be diluted in 50 ml of 5% Dextrose or 0.9% Sodium Chloride.

Prevention of postoperative nausea and vomiting: No dilution is required for **Osetron®** *I.V. & I.M. (only for adults and children over 12 years of age)* administration.

Dosage adjustment for patients with impaired renal function: The dosage recommendation is the same as for the general population.

Dosage adjustment for patients with impaired hepatic function: In patients with severe hepatic impairment, a single maximal daily dose of 8 mg to be infused over 15 minutes beginning 30 minutes before the start of the emetogenic chemotherapy is recommended.

Contraindications
Ondansetron is contraindicated for patients known to have hypersensitivity to the Ondansetron or to any of its ingredient.

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 distention.

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.

Pregnancy & lactation
There are no adequate and well controlled studies in pregnant women. This drug should be used during pregnancy is therefore not recommended expect for compelling reasons. Ondansetron is excreted in the breast milk of rats. 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
Ondansetron does not itself appear to induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system of the liver. Because Ondansetron is metabolized by hepatic cytochrome P-450 drug-metabolizing enzymes, inducers or inhibitors of these enzymes may change the clearance and, hence, the half-life of Ondansetron. On the basis of limited available data, no dosage adjustment is recommended for patients on these drugs.

Overdose
There is no specific antidote for Ondansetron overdose. If overdose is occurred, symptomatic and supportive therapy should be given as appropriate.

Pharmaceutical precautions
Store in a cool and dry place below 30°C. Protect from light.

Presentation
Osetron® Tablet: Each tablet contains Ondansetron 8mg as Hydrochloride USP.

Osetron® Injection: Each ml contains Ondansetron 2mg as Hydrochloride USP.

Osetron® Syrup: Each 5ml syrup contains Ondansetron 4mg as Hydrochloride USP.

Package quantites

Osetron® 8 mg Tablet: Carton of 30 tablets.

Osetron® Injection: Carton of 5 ampoules.

Osetron® Syrup: Bottle of 50 ml.

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