WARNINGS
Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonist.

DOSAGE AND ADMINISTRATION

Prevention of Nausea and Vomiting Associated with Initial and Repeat Courses of Emetogenic Chemotherapy

Ondansetron Hydrochloride Injection should be diluted in 50 mL of 5% Dextrose Injection or 0.9% Sodium Chloride Injection before administration.

Adults: The recommended adult intravenous dosage of ONDANSETRON is three 0.15-mg/kg doses up to a maximum of 16 mg per dose. The first dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg up to a maximum of 16 mg per dose) are administered 4 and 8 hours after the first dose of ONDANSETRON.

Prevention of Postoperative Nausea and Vomiting

Ondansetron Hydrochloride Injection should not be mixed with solutions for which physical and chemical compatibility have not been established. In particular, this applies to alkaline solutions as a precipitate may form.

Adults: The recommended adult intravenous dosage of ONDANSETRON is 4 mg undiluted administered intravenously in not less than 30 seconds, preferably over 2 to 5 minutes, immediately before induction of anesthesia, or postoperatively if the patient did not receive prophylactic antiemetics and experiences nausea and/or vomiting occurring within 2 hours after surgery. Alternatively, 4 mg undiluted may be administered intramuscularly as a single injection for adults. While recommended as a fixed dose for patients weighing more than 40 kg, few patients above 80 kg have been studied. In patients who do not achieve adequate control of postoperative nausea and vomiting following a single, prophylactic, preinduction, intravenous dose of ondansetron 4 mg, administration of a second intravenous dose of 4 mg ondansetron postoperatively does not provide additional control of nausea and vomiting.

Dosage Adjustment for Patients with Impaired Renal Function:
The dosage recommendation is the same as for the general population. There is no experience beyond the first-day administration of ondansetron.

Dosage Adjustment for Patients with Impaired Hepatic Function:In patients with severe hepatic impairment (Child-Pugh2 score of 10 or greater), 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. There is no experience beyond first-day administration of ondansetron.

Stability: Ondansetron Hydrochloride Injection I.P is stable at room temperature under normal lighting conditions for 48 hours after dilution with the following I.V. fluids: 0.9% sodium chloride injection, 5 % dextrose injection, 5% dextrose and 0.9% sodium chloride injection, 5% dextrose and 0.45% sodium chloride injection, and 3% sodium chloride injection.

Although ondansetron injection, I.P is chemically and physically stable when diluted as recommended, sterile precautions should be observed because diluents generally do not contain preservative. After dilution, do not use beyond 24 hours.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration before administration whenever solution and container permit.

PRESENTATION

Ondansetron Hydrochloride Injection. I.P, 2 mg/mL, is a clear, colorless solution filled in clear glass ampoule

STORAGE : Store protected from light, at a temperature not exceeding 30º C.
Improper storage may deteriorate the product

Manufactured by:
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Care & Cure with Research
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For the use of a Registered Medical Practioner or a Hospital or a Laboratory only.

℞ Ondansetron Hydrochloride Injection IP

AMERICAN
ONDICAN 4
Injection

For IV / IM Use Only

Composition :
Each ml contains :
Ondansetron Hydrochloride IP
Eq. to Ondansetron..... 2mg
Methyl Paraben IP.....0.1%w/v
(As preservative)
Propyl Paraben IP.....0.01%w/v
(As preservative)
Water for Injections IP.....q.s.

DESCRIPTION
The active ingredient in Ondansetron Hydrochloride Injection, I.P is the ondansetron hydrochloride (HCl), the racemic form of ondansetron and a selective blocking agent of the serotonin 5-HT3 receptor type.
The empirical formula is C18H19N3O - HCl - 2H2O, representing a molecular weight of 365.9.
Ondansetron HCl is a white to off-white powder that is soluble in water and normal saline.
Ondansetron Injection, I.P is a clear, colorless, nonpyrogenic, sterile solution. The pH of the injection solution is 3.3 to 4.0.

CLINICAL PHARMACOLOGY

Pharmacodynamics:
Ondansetron is a selective 5-HT3 receptor antagonist. While ondansetron's mechanism of action has not been fully characterized, it 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 in chemotherapy-induced nausea and vomiting 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. In humans, urinary 5-HIAA (5-hydroxyindoleacetic acid) excretion increases after cisplatin administration in parallel with the onset of vomiting. The released serotonin may stimulate the vagal afferents through the 5-TH3 receptors and initiate the vomiting reflex.In normal volunteers, single I.V. doses of 0.15 mg/kg of ondansetron had no effect on esophageal motility, gastric motility, lower esophageal sphincter pressure, or small intestinal transit time. In another study in six normal male volunteers, a 16-mg dose infused over 5 minutes showed no effect of the drug on cardiac output, heart rate, stroke volume, blood pressure, or electrocardiogram (ECG).Multiday administration of ondansetron has been shown to slow colonic transit in normal volunteers. Ondansetron has no effect on plasma prolactin concentrations.
In a gender-balanced pharmacodynamic study (n=56), ondansetron 4 mg administered intravenously or intramuscularly was dynamically similar in the prevention of nausea and vomiting using the ipecacuanha model of emesis.
Ondansetron does not alter the respiratory depressant effects produced by alfentanil or the degree of neuromuscular blockade produced by atracurium. Interactions with general or local anesthetics have not been studied.

INDICATIONS AND USAGE
1.] Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Efficacy of the 32 mg single dose beyond 24 hours in these patients has not been established.
2.] Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, ondansetron injection, IP is recommended even where the incidence of postoperative nausea and/or vomiting is low. For patients who do not receive prophylactic ondansetron injection,I.P and experience nausea and/or vomiting postoperatively, ondansetron