

Onstar

Ondansetron USP Orally Disintegrating Tablet &
Ondansetron Hydrochloride USP Oral solution

COMPOSITION

Onstar 8 ODT : Each Orally Disintegrating tablet contains Ondansetron USP 8 mg.

Onstar 50 ml Oral Solution: Each 5 ml oral solution contains Ondansetron hydrochloride dihydrate USP equivalent to Ondansetron 4 mg.

DESCRIPTION

Onstar ODT is a preparation of Ondansetron base, **Onstar** oral solution is the preparation of Ondansetron Hydrochloride USP, the racemic form of Ondansetron which is a selective 5-HT₃ receptor antagonist.

INDICATIONS

Onstar ODT & Oral Solution is indicated for:

The management of nausea and vomiting induced by cytotoxic chemotherapy, for the prevention and treatment of post-operative nausea and vomiting and for the prevention of nausea and vomiting associated with radiotherapy, either total body irradiation or single high dose fraction or daily fractions to the abdomen.

DOSAGE AND ADMINISTRATION

Instructions for use **Onstar** ODT:

With dry hands, push back the foil of 1 tablet and gently remove the tablet. Immediately place the **Onstar** ODT on top of the tongue where it will dissolve in seconds, then swallow with saliva. Administration with liquid is not necessary.

Prevention of nausea and vomiting associated with emetogenic cancer chemotherapy:

Adults : The recommended adult oral dosage is one 8 mg **Onstar** ODT or 10 ml Oral Solution 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. One 8 mg **Onstar** ODT or 10 ml Oral Solution given twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

Children : Patients 12 years of age and older, the dosage is the same as for adults. Patients 4 to 11 years of age, the dosage is 5 ml of **Onstar** Oral Solution given 3 times a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with subsequent dose 4 and 8 hours after the first dose. 5 ml of **Onstar** Oral Solution should be administered 3 times a day (every 8 hours) for 1 to 2 days after completion of chemotherapy.

Elderly : **Onstar** ODT/ Oral Solution is well tolerated by patients over 65 years and no alteration of dosage, dosing frequency or route of administration are required.

Prevention of postoperative nausea and vomiting:

Adults: The recommended dosage is 16 mg given as two 8 mg **Onstar** or 20 ml Oral Solution one hour before anesthesia or 8 mg **Onstar** ODT or 10 ml of **Onstar** Oral Solution by mouth an hour before anesthesia followed by 2 further doses of 8 mg or 10 ml of **Onstar** Oral Solution at 8-hour intervals.

Children: Aged 2 years and over may be given up to a maximum dose of 5 ml (4 mg) **Onstar** Oral Solution, both for prevention & treatment of postoperative nausea and vomiting.

Elderly: The dosage is the same as for the adults.

Prevention of nausea and vomiting associated with radiotherapy

Adults :The recommended adult oral dosage is one 8 mg **Onstar** ODT or 10 ml Oral Solution given 3 times a day. *For total body irradiation*, one 8 mg **Onstar** ODT or 10 ml of **Onstar** 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, one 8 mg **Onstar** ODT or 10 ml of **Onstar** 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, one 8 mg **Onstar** ODT or 10 ml of **Onstar** Oral Solution should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day radiotherapy is given.

Children : There is no experience with the use of **Onstar** ODT or **Onstar** Oral Solution in the prevention of

radiation induced nausea and vomiting in pediatric patients of 4 years or younger.

Elderly: Efficacy and tolerance in patients over 65 years was similar to that seen in younger adults indicating no need to alter dosage or route of administration in the elderly.

CONTRAINDICATIONS

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

PRECAUTIONS

Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5-HT₃ receptor antagonists. As Ondansetron is known to increase large bowel transit time, patients with signs of sub acute intestinal obstruction should be monitored following administration.

DRUG INTERACTION

Potent inducers (i.e. phenytoin, carbamazepine and rifampicin) of CYP3A4 : The oral clearance of Ondansetron was increased and Ondansetron blood concentrations were decreased. Tramadol: Data from small studies indicate that Ondansetron may reduce the analgesic effect of tramadol.

SIDE-EFFECTS

Headache, a sensation of flushing or warmth, hiccups, constipation may occur. Blurred vision, chest pain with or without ST segment depression, cardiac arrhythmias, hypotension and bradycardia have been rarely reported.

USE IN PREGNANCY & LACTATION

Pregnancy category B. Reproduction studies at daily oral dose up to 10 and 30 mg/kg/day have been performed in animals and have revealed no evidence of impaired fertility harm to the fetus due to Ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Tests have shown that Ondansetron passes into the milk of lactating animals. It is not known whether Ondansetron is excreted in human milk. Caution should be exercised when Ondansetron is administered to nursing women.

PHARMACEUTICAL PRECAUTION

Keep away from light, store in a cool (below 30° C for **Onstar** ODT tablet and dry place. Keep out of reach of children. Do not keep **Onstar** oral solution in freeze.

COMMERCIAL PACKS

Onstar 8 ODT: Each Box containing 3X10 tablets of blister packs.

Onstar Oral Solution: Each amber glass bottle contains 50 ml oral solution.

Manufactured by



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.