Ofran™

Ondansetron

COMPOSITION

Ofran™ 8 mg Tablet: Each tablet contains Ondansetron 8mg as Ondansetron hydrochloride USP.
Ofran™ oral solution 50 ml: Each 5 ml solution contains Ondansetron 4 mg as Ondansetron hydrochloride USP.
Ofran™ injection 4 ml: Each 4ml injection contains Ondansetron 8 mg as Ondansetron hydrochloride USP.
Ofran™ suppository 16 mg: Each 16 mg suppository contains Ondansetron 16 mg as Ondansetron hydrochloride USP.

PHARMACOLOGY

Ofran™ (Ondansetron) is a selective $5HT_3$ receptor antagonist. While its mechanism of action has not been fully characterized, **Ofran**™ (Ondansetron) is not a dopamine-receptor antagonist. **Ofran**™ (Ondansetron) is well absorbed from the gastrointestinal tract and undergoes some first-pass metabolism.

INDICATION

Ofran™ is indicated for

- Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy
- Prevention of nausea and vomiting associated with radiotherapy
- Prevention of post operative nausea and vomiting

DOSAGE & ADMINISTRATION

Prevention of chemotherapy induced nausea & vomiting (CINV):
Adult- tablet and oral solution: The recommended adult oral dosage of **Ofran**™ (Ondansetron) is 24 mg given as three 8 mg tablets in highly emetogenic chemotherapy. In case of moderately emetogenic chemotherapy the oral dose is one 8mg **Ofran**™ (Ondansetron) tablet or 10 ml of **Ofran**™ (Ondansetron) oral solution given twice daily. *Injection:* The recommended i.v. dose of **Ofran**™ (Ondansetron) is a single 32 mg dose or three 0.15 mg/kg doses. A single 32 mg dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg) are administered 4 and 8 hours after the first dose of **Ofran**™. *Suppository:* The recommended adult dose is one 16 mg suppository 1-2 hours before treatment. Ondansetron should be continued for upto 5 days after a course of treatment. The recommended dose is one suppository daily.
Pediatric patients- tablet and oral solution- for pediatric patients 4 through 11 years of age the dosage is one 4mg **Ofran**™ tablet or 5ml of **Ofran**™ solution should be administered 3 times a day for 1 to 2 days after completion of chemotherapy. *Injection:* the dosage in pediatric patients 4 to 18 years of age should three 0.15-mg/kg doses. *Suppository:* Not recommended.
Radiotherapy induced nausea and vomiting:
Adult- tablet and oral solution: the recommended oral dosage is one 8mg **Ofran**™ tablet or 10ml of **Ofran**™ oral solution given 3 times daily.
Post operative nausea & vomiting (PONV):
Adult- tablet and oral solution: the recommended dosage is 16 mg given as two 8mg **Ofran**™ tablets or 20 ml of **Ofran**™ oral solution 1hour before induction of anesthesia. *Injection:* The recommended I.V. dosage of **Ofran**™ for adults 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 experiences nausea and/or vomiting occurring shortly after surgery. Alternatively, 4 mg undiluted may be administered intramuscularly as a single injection for adults. In patients who do not achieve adequate control of postoperative nausea and vomiting following a single, prophylactic, preinduction, I.V. dose of Ondansetron 4 mg, administration of a second I.V. dose of 4 mg Ondansetron postoperatively does not provide additional control of nausea and vomiting. *Suppository:* The recommended adult dose is one 16 mg suppository 1-2 hours before treatment. Ondansetron should be continued for upto 5 days after a course of treatment. The recommended dose is one suppository daily.
Pediatric patients- The recommended I.V. dosage of **Ofran**™ for pediatric patients (2 to 12 years of age) is a single 0.1-mg/kg dose for pediatric patients weighing 40 kg or less, or a single 4-mg dose for pediatric patients weighing more than 40 kg. The rate of administration should not be less than 30 seconds, preferably over 2 to 5 minutes. Little information is available about dosage in pediatric patients younger than 2 years of age. Suppository: Not recommended.
Dosage adjustment for patients with impaired hepatic function-
Tablet and Oral Solution- The total daily dose of 8 mg should not be exceeded.
Injection- A single maximal dose of 8 mg to be infused over 15 minutes beginning 30 minutes before the start of the emetogenic chemotherapy is recommended. *Suppository:* Not recommended

CONTRAINDICATION

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

WARNINGS & PRECAUTION

Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other 5-HT_3 receptor antagonists.
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.

ADVERSE EFFECTS

The most common adverse effects include headache, constipation, diarrhea. In chemotherapy induced nausea and vomiting rash has occurred in approximately 1% of patients receiving Ondansetron. Blurred vision, chest pain with or without ST segment depression, cardiac arrhythmias, hypotension and bradycardia have been rarely reported.

DRUG INTERACTIONS

In patients treated with potent inducers of CYP3A4 (i.e Phenytoin, Carbamazepine or Rifampicin), the oral clearance of Ondansetron was increased and Ondansetron blood concentrations were decreased. Data from small studies indicate that Ondansetron may reduce the analgesic effect of tramadol.

USE IN PREGNANCY AND LACTATION

In pregnancy: Pregnancy category B. Reproduction studies at daily oral dose up to 10 and 30mg/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. So the drug should be used in pregnancy only if clearly needed.
In lactation: Ondansetron excretes in milk of lactating animals. Caution should be exercised when Ondansetron is administered to nursing mother.

STORAGE

Store in a cool and dry place, protected from light and moisture. *For suppository-* Store below 25^0 c.

HOW SUPPLIED

Ofran™ 8 mg tablet: Each box contains 30 tablets in blister pack
Ofran™ oral solution: Each bottle contains 50 ml solution in PET bottle
Ofran™ injection 4 ml: Each box contains 6 ampoules in blister pack
Ofran™ suppository 16 mg: Each box contains 10 suppositories in blister pack

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH