Ofran®

Ondansetron

COMPOSITION

Ofran® tablet: Each tablet contains Ondansetron 8mg as Ondansetron Hydrochloride Dihydrate BP.
Ofran® oral solution: Each 5ml solution contains Ondansetron 4mg as Ondansetron Hydrochloride Dihydrate BP.
Ofran® Injection: Each 4 ml solution contains Ondansetron 8 mg as Ondansetron Hydrochloride Dihydrate 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 8 mg **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 the first dose of **Ofran®**.

Pediatric patients-Tablet and oral solution: for pediatric patients 4 through 11 years of age the dosage is one 4 mg **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 be three 0.15 mg/kg doses.

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 3times daily.*

Post operative nausea & vomiting (PONV):
Adult-Tablet and oral solution: the recommended dosage is 16 mg given as two 8 mg **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.

Pediatric patients: The recommended i.v. dose 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 less than 30 seconds, preferably over 2 to 5 minutes. Little information is available about dosage in the pediatric patients younger than 2 years of age.
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.

CONTRAINDICATION

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

WARNINGS & PRECAUTION

Hypersensitivity reactions have been reported in patients who have exhibited hyper sensitivity to other 5-HT3 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 EFFECT

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 INTERACTION

In patients treated with potent inducers of CYP3A4 (i.e Phenytoin, Carbamazepine or Rifampicin), the 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 below 30° C. Protect from light. Keep all the medicines out of the reach of the children.

HOW SUPPLIED

Ofran® tablet: Each box contains 30 tablets in blister pack.
Ofran® oral solution: Each bottle contains 50 ml solution in pet bottle.
Ofran® injection: Each box contains 6 ampoules in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH