

# EMISTON

## ONDANSETRON USP

### Compositions:

Emiston- 8 Tablet: Each film coated tablet contains Ondansetron USP 8 mg. Emiston Oral Solution: Each 5 ml contains Ondansetron Hydrochloride Dihydrate USP equivalent to Ondansetron USP 4 mg. Emiston 4 ml IV/IM injection: Each ml injection contains Ondansetron USP 2 mg.

### Pharmacology:

Emiston (Ondansetron) is a selective 5-HT<sub>3</sub> receptor antagonist. While its mechanism of action has not been fully characterized, Ondansetron is not a dopamine-receptor antagonist. Serotonin receptors of the 5-HT<sub>3</sub> 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 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.

### Dosage And Administration:

Oral: Moderately emetogenic chemotherapy or radiotherapy: 8 mg 1-2 hours before treatment, then 8 mg every 12 hours for up to 5 days. Severely emetogenic chemotherapy: 8 mg every 12 hours for up to 5 days. Children: 4 mg every 12 hours for up to 5 days. Prevention of postoperative nausea and vomiting: 16 mg 1 hour before anaesthesia followed by 8 mg at 8 hour intervals for 2 further doses. Oral Solution: Prevention of chemotherapy induced nausea & vomiting: Adult: The recommended adult oral dosage is Emiston (Ondansetron) 10 ml oral solution thrice daily in highly emetogenic chemotherapy. In case of moderately emetogenic chemotherapy the oral dose is 10 ml Emiston (Ondansetron) given twice daily. Pediatric Patient: For Pediatric patients 4 through 11 years of age should be given 5 ml oral solution 3 times a day for 1 to 2 days after completion of chemotherapy. Radiotherapy induce nausea and vomiting: The recommended adult oral dosage is Emiston (Ondansetron) 10 ml oral solution thrice daily. Post operative nausea and vomiting: The recommended adult oral dosage is 20 ml of Emiston (Ondansetron) oral solution 1 hour before induction of anesthesia. Moderately emetogenic chemotherapy or radiotherapy: By IM or slow IV injection, 8 mg immediately before treatment. Severely emetogenic chemotherapy: By IM or slow IV injection, 8 mg immediately before treatment, when necessary followed by 8 mg at intervals of 2-4 hours for further doses. Child: By slow IV injection 5 mg/m<sup>2</sup> immediately before chemotherapy. Prevention of postoperative nausea and vomiting: By IM or slow IV injection 4 mg at induction of anaesthesia. Child over 2 years: By slow IV injection, 100 mcg/kg (maximum 4 mg) before, during or after induction of anaesthesia. Treatment of postoperative nausea and vomiting: By IM or slow IV injection, 100 mcg/kg (maximum 4 mg).

### Contraindications:

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

### Warning And Precaution:

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.

### Side Effects:

Generally Ondansetron is well tolerated. However, few side effects including headache,

diarrhea, fatigue, dizziness and constipation may be seen after Ondansetron is administered.

**Use in Pregnancy and Lactation:**

Pregnancy: There are, however, no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Nursing mother: 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 Interaction:**

The following drugs should be used with caution when concomitantly used with Ondansetron: Phenytoin, Carbamazepine, Rifampicin & Tramadol.

**Overdosage:**

There is no specific antidote for Ondansetron overdose. Hypotension (and faintness) occurred in a patient that took 48 mg of Ondansetron tablets daily.

**Storage:**

Store in a cool (below 30°C) and dry place. Keep away from light and out of reach of children.

**Packing:**

Emiston -8 Tablet: Each box contains 3x10's tablets in blister strip. Emiston Oral Solution: Each PET bottle contains 50 ml oral solution. Emiston 4ml IV/IM injection: Each box contains 5x1's ampoules of 4 ml.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.