NOVARTIS

# **ZOFRAN™** (ondansetron hydrochloride dihydrate)

Zofran plastic ampoules 2ml and 4ml

## Basic Succinct Statement (BSS)

## CODE: PI RD 26 JUN 15; APPR 9 MAR 16

## ZOFRAN™

**Important note:** Before prescribing, consult full prescribing information.

**Presentation:** ***Ondansetron hydrochloride dihydrate***: ♦Solution for injection or infusion: 2 mg/mL.

**Indications:** **Adults:** ♦ Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy**.** ♦ Prevention and treatment of post-operative nausea and vomiting.

**Children and Adolescents:** ♦Management of nausea and vomiting induced by cytotoxic chemotherapy. ♦I.V. (only): recommended for prevention or treatment of post-operative nausea and vomiting.

### Dosage and administration:

♦***Chemotherapy And Radiotherapy Induced Nausea And Vomiting (CINV and RINV)*****: Recommended dose (Adults):** ♦Injection: 8 mg i.v. or i.m. dose as a slow injection immediately before treatment. For HEC a maximum initial dose of 16 mg IV infused over 15 minutes. Initial dose can be followed by two additional 8 mg I.V. or I.M. doses 2 to 4 hours apart

♦***CINV*****: Children and Adolescents (3 years to 17 years):** ♦ Injection: dose should be given immediately before chemotherapy as a single i.v dose. I.V dose must not exceed 8 mg. Oral dose can commence 12 hours later. Dose calculate by: **body surface area** (BSA): 5 mg/$m^2$ i.v. dose. By **body weight**: 0.15 mg/kg i.v. dose.

♦***Post-Operative nausea and vomiting (PONV):*** **Recommended dose (Adults):** ♦Injection: Single dose of 4 mg by i.m. or slow i.v. injection administered at the induction of anesthesia. ♦**Recommended dose Children and Adolescents (3 years to 17 years):** ♦Injection: Slow i.v. injection (not less than 30 seconds) at a dose of 0.1 mg/kg up to a maximum of 4 mg.

**Special populations:** ♦**Elderly (>65 years):** I.V.: All doses must be diluted, infused over 15 min and if repeated, given no less than 4 hours apart. ♦**>75 years:** the initial dose should not exceed 8 mg. ♦**Renal impairment:** No dose adjustment is required. ♦**Hepatic impairment:** Moderate or severe: total daily dose of 8 mg should not be exceeded. ♦**Patients with Poor Sparteine/Debrisoquine Metabolism:** No dose adjustment required.

**Contraindications:** ♦Concomitant use with Apomorphine. ♦Hypersensitivity to any component of the preparation.

**Warnings and precautions:** ♦Caution in patients with prolongation of QTc, cases of Torsade de Pointes have been reported. Hypokalemia and hypomagnesemia should be corrected prior to treatment. ♦Hypersensitivity reactions to other 5HT3 receptor antagonists. Appropriate observation of the patient in case of concomitant administration of other serotonergic drugs. ♦Patients with signs of subacute intestinal obstruction should be monitored.

**Pregnancy:** Not recommended.

**Breast-feeding:** Not recommended.

**Adverse drug reactions:** ♦**Very common (≥10%):** Headache. ♦**Common (1 to 10%):** Sensation of warmth or flushing, constipation, local burning sensation, local IV injection site reactions. ♦**Uncommon (0.1 to 1%):** Seizures, movement disorders (including extrapyramidal reactions such as dystonic reactions, oculogyric crisis and dyskinesia), arrhythmias, chest pain with or without ST segment depression, bradycardia, hypotension, hiccups, asymptomatic increases in liver function tests. ♦**Rare (0.01 to 0.1%):** Immediate hypersensitivity reactions sometimes severe, including anaphylaxis, dizziness predominantly during rapid IV administration, transient visual disturbances (e.g. blurred vision) predominantly during IV administration, QTc prolongation (including Torsade de Pointes). ♦**Very rare (≤0.01%):** Transient blindness predominantly during IV administration, toxic skin eruption, including toxic epidermal necrolysis.

**For a complete list of ADRs, refer to the full prescribing information.**

**Interactions**: ♦Ondansetron may reduce the analgesic effect of tramadol. ♦Caution with drugs that prolong QT interval/cause electrolyte abnormalities. ♦Contraindicated with apomorphine. ♦Caution with potent CYP3A4 inducers. ♦Caution with other serotonergic drugs. See Contraindications and Warnings and precautions.