NOVARTIS

ZOFRAN® (ondansetron hydrochloride dihydrate)

4 mg and 8 mg Film-coated tablets

Basic Succinct Statement (BSS)

CODE: BSS RD 3 APR 20; APPR 27 NOV 20

This material is only meant for Healthcare Professionals

ZOFRAN®

Important note: Before prescribing, consult full prescribing information.

Presentation: ***Ondansetron hydrochloride dihydrate***: ♦Film-coated tablets: 4 mg and 8 mg.

Indications:

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

Children and Adolescents: ♦Management of nausea and vomiting induced by cytotoxic chemotherapy.

Dosage and administration:

♦***Chemotherapy And Radiotherapy Induced Nausea And Vomiting (CINV and RINV)*****: Recommended dose (Adults):** ♦ 8 mg 1 to 2 h before treatment, followed by 8 mg orally 12 h later for a max of 5 days. For high emetogenic chemotherapy (HEC) up to 24 mg taken together with 12 mg oral dexamethasone sodium phosphate, 1 to 2 h before treatment.

♦***CINV*****: Children and Adolescents (3 years to 17 years):** ♦ Zofran 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 and may be continued for up to 5 days. 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):** ♦ 16 mg given 1 h prior to anesthesia.

Special populations: ♦**Elderly (>65 years):** Oral: No dose adjustment required. ♦**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 $5HT_3$ 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.

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.