Adults and Pediatric patients (6 months to 18 years): Three 0.15 mg/kg doses, up to a maximum of 16 mg.

**INDICATIONS AND USAGE**

**Initial and Repeat Courses of Emetogenic Cancer Chemotherapy**

- Prevention of nausea and vomiting associated with chemotherapy
- Prevention of nausea and vomiting associated with high-dose cisplatin
- Prevention of perioperative nausea and vomiting
- Prevention of postoperative nausea and vomiting

**Prevention of Nausea and Vomiting with Ondansetron**

- For patients following abdominal surgery or in patients with chemotherapy-induced nausea and vomiting

**Pharmacokinetics**

- Ondansetron is extensively metabolized and elimination is primarily by hepatic metabolism, with only minor amounts excreted in the urine.

**Adverse Reactions**

- Rates of these reactions were not significantly different in the ondansetron and placebo groups.

**Contraindications**

- History of anaphylactic reaction to ondansetron
- Pregnancy (category C) with the exception of women with metastatic breast cancer

**Warnings and Precautions**

- CYP2D6 metabolic phenotype
- Patients with congenital long QT syndrome

**Dosage and Administration**

- Administration should be under the supervision of a physician experienced in the treatment of patients who are vomiting or at risk of vomiting.

**DRUG INTERACTIONS**

- Concomitant use with ondansetron is contraindicated.

**SUPPLIED/STORAGE AND HANDLING**

- Store at room temperature (15° to 30°C [59° to 86°F]) and protect from light.

**NURSING MOTHERS**

- There is no information on the excretion of ondansetron in human milk. Because many drugs are excreted in human milk, caution should be exercised when ondansetron is administered to a nursing woman.

**ADVERSE REACTIONS**

- In clinical trials, adverse reactions were not significantly different in the ondansetron and placebo groups.

**DRUG ABUSE AND DEPENDENCE**

- Ondansetron is not subject to abuse or dependence.

**OVERDOSAGE**

- Symptoms: Hypokalemia, hypomagnesemia, dehydration, cardiovascular disturbances, and electrolyte abnormalities.

**DOSAGE FORMS AND STRENGTHS**

- Oral: Tablets 4 mg
- Injectable: Solution 4 mg/mL

In a single-blind placebo-controlled study of 460 patients undergoing major surgery, patients who received ondansetron had a significantly lower incidence of emetic episodes (52% versus 81%) compared to those who received placebo.

In another study involving 124 patients undergoing major surgery, those who received ondansetron had a significantly lower incidence of emetic episodes (55% versus 82%) compared to those who received placebo.

In a study of 51 pediatric patients (1 month to 24 months of age) who were undergoing surgery requiring general anesthesia, eight patients (25%) received routine prophylactic ondansetron. Eighteen patients (25%) received routine prophylactic ondansetron. Eighteen patients (25%) received routine prophylactic ondansetron.

A double-blind, placebo-controlled study was conducted to evaluate the efficacy of ondansetron in preventing emesis in 285 patients undergoing major surgery. Patients were randomized to receive either ondansetron (4 mg intravenously) or placebo. The results showed a significantly lower incidence of emetic episodes in the ondansetron group compared to the placebo group.

A randomized, double-blind, placebo-controlled study was conducted to evaluate the efficacy of ondansetron in preventing emesis in 554 patients undergoing major surgery. Patients were randomized to receive either ondansetron (4 mg intravenously) or placebo. The results showed a significantly lower incidence of emetic episodes in the ondansetron group compared to the placebo group.

In a double-blind, placebo-controlled study of 196 patients undergoing major surgery, those who received ondansetron had a significantly lower incidence of emetic episodes (55% versus 82%) compared to those who received placebo.

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