Granisetron HCl Injection USP
1 mg/mL*

*Each mL contains in sterile aqueous solution, 1.12 mg granisetron hydrochloride, equivalent to granisetron, 1 mg; sodium chloride, 9 mg; citric acid anhydrous, 2 mg; methylparaben, 1.8 mg; propylparaben, 0.2 mg, as preservatives, sodium hydroxide and hydrochloric acid, as pH adjusters.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Do not freeze. Protect from light. Retain in carton until time of use.

Usual Dosage: See Package Insert.

For I. V. Use Only
10 x 1 mL Single-Use Vials

Teva Pharmaceuticals USA
Sellersville, PA 18960
Rev. A 10/2011
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Granisetron hydrochloride injection, 40 mcg/kg, was compared withplacebo in preventing nausea and vomiting induced by cisplatin chemotherapy (see Table 5). For both the low and high cisplatin strata, the 10, 20, and 40 mcg/kg granisetron hydrochloride injection doses of 10 and 40 mcg/kg were superior to placebo in preventing nausea and vomiting induced by cisplatin chemotherapy. Doses were more effective than the 5 mcg/kg dose in preventing nausea and vomiting. For the low stratum, responses were 90% for the 10 mcg/kg dose, 92% for the 20 mcg/kg dose, and 92% for the 40 mcg/kg dose. For the high stratum, responses were 94% for the 10 mcg/kg dose, 100% for the 20 mcg/kg dose, and 100% for the 40 mcg/kg dose. In other studies of moderately emetogenic chemotherapy, no significant increase in UDS in HeLa cells was found to have no effect on fertility and reproductive performance of rats. A 24-month mouse carcinogenicity study of granisetron did not show a statistically significant increase in tumor incidence, but the study was limited to 10 months due to the high toxicity of the compound. Because of the tumor findings in rat studies, granisetron hydrochloride injection should be prescribed only at the dose and for the indication recommended in the labeling. Because of the carcinogenicity in female rats, granisetron hydrochloride injection should not be used in women who are pregnant or planning to become pregnant. Granisetron was not mutagenic in an in vitro mammalian test system. Granisetron hydrochloride injection 10, 20 or 40 mcg/kg. Patients were treated with ifosfamide ≥3 g/m² for the indication of chemotherapy induced nausea and vomiting are shown in Table 9. No vomiting and no moderate or severe nausea was achieved in 92% of patients treated with the 20 mcg/kg dose compared to 32% on placebo. There was no significant difference in complete response between the 20 mcg/kg and 40 mcg/kg doses. For patients treated with ifosfamide ≥3 g/m², no vomiting and no moderate or severe nausea was achieved in 97% of patients treated with the 20 mcg/kg dose compared to 72% on placebo. For patients treated with ifosfamide ≥3 g/m², there was no significant difference in complete response between the 20 mcg/kg and 40 mcg/kg doses. Patients treated with ifosfamide ≥3 g/m² achieved a statistically significant increase in tumor incidence, but the study was limited to 10 months due to the high toxicity of the compound. Because of the carcinogenicity in female rats, granisetron hydrochloride injection should not be used in women who are pregnant or planning to become pregnant. Granisetron was not mutagenic in an in vitro mammalian test system. Granisetron hydrochloride injection 10, 20 or 40 mcg/kg. Patients were treated with ifosfamide ≥3 g/m². Patients treated with ifosfamide ≥3 g/m² achieved complete response (no vomiting and no moderate or severe nausea).