Granisetron HCl Injection USP
4 mg/4 mL (1 mg/mL)*

For I.V. Use Only
4 mL Multi-Use Vial

Discard unused portion 30 days after vial penetration.

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 and propylparaben, 0.2 mg as preservatives. Sodium hydroxide and hydrochloric acid, as pH adjusters.

Usual Dosage: See Package Insert.

Discard unused portion 30 days after vial penetration.

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Teva Pharmaceuticals USA
Sellersville, PA 18960

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.
See bottom panel for lot number and expiration date.
Usual Dosage:

4 mg/4 mL

Reference ID: 3115038
Granisetron hydrochloride injection USP is a serotonin-3 (5-HT3) receptor antagonist indicated for:

- Prevention of chemotherapy-induced nausea and vomiting
- Prevention of postoperative nausea and vomiting
- Chemotherapy for small cell lung cancer

**INDICATIONS AND USAGE**

Granisetron hydrochloride injection USP is indicated for the prevention of postoperative nausea and vomiting (PONV) with or without antiemetics in patients undergoing anesthesia and surgical procedures in which emesis is a risk. It is also indicated for the prevention of chemotherapy-induced nausea and vomiting (CINV) associated with cisplatin-based chemotherapy. Additionally, it is used for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose emetogenic chemotherapy.

**CONTRAINDICATIONS**

- Hypersensitivity to granisetron or any component of the formulation
- Patients with pre-existing moderate to severe constipation
- Patients with pre-existing obstructive intestinal disease

**WARNINGS AND PRECAUTIONS**

- QT prolongation has been reported with granisetron hydrochloride. Use with caution in patients with cardiac disease.
- Use with caution in patients with a history of QT prolongation, hypokalemia, hypomagnesemia, or a history of drug-induced QT prolongation.
- Use with caution in patients with a history of cardiac conduction disturbances.

**ADVERSE REACTIONS**

- The most common adverse reactions include headache, sweating, diarrhea, and constipation.
- Other reported adverse reactions include fever, taste disorder, skin rashes, agitation, anxiety, CNS stimulation, and insomnia.

**DOSAGE FORMS AND CONTENTS**

Granisetron hydrochloride injection USP may be administered intravenously as a single 10 mcg/kg dose, repeated every 24 hours as required. There are no data on the safety or effectiveness of using granisetron hydrochloride injection USP in children under 1 year of age.

**STABILITY**

Granisetron hydrochloride injection USP is stable for at least 24 hours when prepared at the time of administration. However, granisetron hydrochloride solution should be used within 24 hours of preparation. Storing the solution in the refrigerator does not alter its stability.

**HOW SUPPLIED/STORAGE AND HANDLING**

Granisetron hydrochloride injection USP is supplied as a sterile solution in 2-mL, 5-mL, and 10-mL vials. The solution should be stored at room temperature and protected from light. The solution should be inspected for particulate matter and discoloration before administration.

**REFERENCES**

- All information available in the Reference Section.

**PATIENT COUNSELING INFORMATION**

- The HIGHLIGHTS OF PRESCRIBING INFORMATION should be reviewed with the patient before starting therapy.

**FULL PRESCRIBING INFORMATION**

- The full prescribing information should be reviewed for complete details of Granisetron hydrochloride injection USP.
Moderately Emetogenic Chemotherapy

The combination of chlorpromazine (50 to 200 mg/24 hours) and granisetron hydrochloride injection, 40 mcg/kg, was compared with chlorpromazine alone in 108 patients. Granisetron hydrochloride injection efficacy remained relatively constant over the first six repeat cycles. After more than 15 cycles, the response rates were 77% (N = 15) for chlorpromazine and 81% (N = 15) for chlorpromazine plus granisetron hydrochloride injection. At 24 hours, 22% of granisetron hydrochloride injection-treated patients were responders, compared with 10% on the chlorpromazine regimen. The combination of chlorpromazine (50 to 200 mg/24 hours) and granisetron hydrochloride injection was significantly more effective than chlorpromazine alone in preventing nausea and vomiting (see Table 8).

In an uncontrolled trial, 512 cancer patients received granisetron hydrochloride injection. Repeat-cyc randomly selected patients received it for at least four cycles. Granisetron hydrochloride injection was also evaluated in a randomized dose comparison study. In that study, 224 patients received it for at least four cycles, and 40 patients did not. The combination of chlorpromazine (50 to 200 mg/24 hours) and granisetron hydrochloride injection was significantly more effective than chlorpromazine alone in preventing nausea and vomiting (see Table 8).

Nitrogen mustardhigh (≥80 to 120 mg/m2) or low (50 to 79 mg/m2) cisplatin dose. Table 7 shows response rates of patients for both cisplatin strata.

Table 6 Prevention of Chemotherapy-Induced Nausea and Vomiting

<table>
<thead>
<tr>
<th></th>
<th>No More Than Moderate Nausea</th>
<th>Complete Responsea</th>
<th>No Nausea</th>
<th>No Vomiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisplatin strata</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>77%</td>
<td>68%</td>
<td>32%</td>
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<tr>
<td>Low</td>
<td>75%</td>
<td>47%</td>
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<td>P-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.012</td>
<td>NS</td>
</tr>
</tbody>
</table>

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(a) Cisplatin administration began within 10 minutes of granisetron hydrochloride injection infusion and continued for 1.5 to 3.0 hours.

(b) No vomiting and no use of rescue antiemetic.

**Elderly**

A pharmacokinetic study in patients with hepatic impairment due to neoplastic disease was conducted. A pharmacokinetic study in patients with hepatic impairment due to neoplastic disease was conducted. The pharmacokinetics of granisetron are similar in pediatric and adult patients.

**Pediatric Patients**

A pharmacokinetic study in pediatric cancer patients (2 to 16 years old) demonstrated that the pharmacokinetic parameters noted in patients, dosage adjustment in patients with hepatic impairment.

**Storage**

Store at 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not freeze. If the ampule is inadvertently frozen, it should be discarded. The ampule should be stored in the protective carton until ready for use.