Composition
Vomidyl tablet: Each tablet contains Ondansetron Hydrochloride Dihydrate USP 9.976 mg equivalent to Ondansetron 8 mg.

Indications and Usage
Ondansetron is a serotonin subtype 3 (5-HT₃) receptor antagonist indicated:
- Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.
- Prevention and treatment of post-operative nausea and vomiting.
- Prevention of radiotherapy induced nausea and vomiting.

Dosage and Administration

<table>
<thead>
<tr>
<th>Chemotherapy-Induced Nausea and Vomiting</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric patients (6 months to 18 years)</td>
<td>Three 0.15 mg/kg doses, up to a maximum of 16 mg per dose.</td>
</tr>
<tr>
<td>Adults</td>
<td>Three 0.15 mg/kg doses, up to a maximum of 16 mg per dose.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiotherapy-Induced Nausea and Vomiting</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>Initial Dose: 8 mg orally 1 to 2 hours before radiotherapy. Post Radiotherapy: 8 mg orally every 8 hours for up to 5 days after a course of treatment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Postoperative Nausea and Vomiting</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>16 mg given as two 8 mg Tablets</td>
</tr>
</tbody>
</table>

Use in Specific Population

**Pregnancy:** Pregnancy Category B

**Nursing Mothers:** Ondansetron is excreted in the breast milk of rats. It is not known whether Ondansetron is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ondansetron is administered to a nursing woman.

**Geriatric Use:** Dose adjustment is not needed in patients over the age of 65.

**Hepatic Impairment:** A total daily dose of 8 mg should not be exceeded (patients with severe hepatic impairment).

**Renal Impairment:** No dosage adjustment is recommended.

Contraindication
- Contraindicated in patients known to have hypersensitive to the drug or any of its components.
- Concomitant use of apomorphine.

Precaution
- Hypersensitivity reactions, including anaphylaxis and bronchospasm, have been reported with or without known hypersensitivity to other selective 5-HT₃ receptor antagonists

Adverse Reaction
The most common adverse reactions in Chemotherapy-induced nausea and vomiting (incidence 7%) are diarrhea, headache and fever.
The most common adverse reactions postoperative nausea and vomiting in adults is headache (incidence 10%), and in pediatric patients aged 1 to 24 months is diarrhea (incidence 2%).

Drug Interaction
The potential for clinically significant drug interactions with Ondansetron appears to be low.

Storage
Keep out of the reach of children. Keep below 30°C, protect from light.

How supplied
Vomidyl tablet: Each box contains 3x10’s tablet in blister pack.

Manufactured for
SMC ENTERPRISE LTD, Zamirdia, Bhaluka, Mymensingh
by Julphar Bangladesh Ltd. Faridpur, Sreepur, Gazipur

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