

NausGo

(Ondansetron orally disintegrating tablets)

Composition:

Each uncoated Orally Disintegrating Tablets contains:

Ondansetron Hydrochloride IP

Eq. to Ondansetron.....4mg Excipients.....q.s.

Clinical Pharmacology:

Ondansetron : Ondansetron is a selective serotonin 5-HT₃ receptor antagonist. It works by blocking 5-HT₃ receptors in the central nervous system and the gastrointestinal tract. This action inhibits the effects of serotonin, a neurotransmitter involved in triggering nausea and vomiting, particularly in response to chemotherapy, radiation, or surgery. By preventing serotonin from binding to its receptors, ondansetron effectively reduces or prevents nausea and vomiting.

Indications:

- Chemotherapy-Induced Nausea and Vomiting
- Radiotherapy-Induced Nausea and Vomiting
- Postoperative Nausea and Vomiting
- Gastroparesis

Contraindications:

- Known Hypersensitivity
- Use with caution in patients with:
- Severe Hepatic Impairment: Requires dose adjustment due to altered metabolism.
- Prolonged QT Interval: Ondansetron can further prolong the QT interval, increasing the risk of arrhythmias.

Precautions and Warnings:

- **QT Interval Prolongation:** Use with caution in patients with a prolonged QT interval or those on medications that prolong QT.
- **Hepatic Impairment:** Dose adjustment is necessary for patients with severe hepatic impairment, as ondansetron is metabolized by the liver.

- **Electrolyte Imbalance:** Correct any electrolyte imbalances before use, as they can increase the risk of arrhythmias.
- **Serotonin Syndrome:** Risk exists when combined with other serotonergic drugs. Monitor for symptoms like agitation, hallucination, and rapid heart rate.
- **Breastfeeding:** It is excreted in breast milk, so caution is advised when used during breastfeeding.
- **Severe Constipation:** May cause or worsen constipation, especially in patients with pre-existing conditions.

Drug Interactions:

- **Apomorphine:** Can cause severe hypotension and loss of consciousness when used with ondansetron.
- **Other QT-Prolonging Drugs:** Co-administration with drugs that prolong the QT interval (e.g., certain antipsychotics or antiarrhythmics) can increase the risk of arrhythmias.
- **Serotonergic Agents:** Concurrent use with other serotonergic drugs (e.g., SSRIs, SNRIs) may increase the risk of serotonin syndrome.
- **CYP3A4 Inhibitors:** Strong inhibitors (e.g., ketoconazole) can increase ondansetron levels, requiring dose adjustment.
- **CYP3A4 Inducers:** Strong inducers (e.g., rifampin) can decrease ondansetron levels, potentially reducing effectiveness.
- **Antiepileptic Drugs:** Some may affect ondansetron metabolism, impacting its effectiveness.

Adverse Effects:

- Headache
- Constipation
- Dizziness
- Fatigue
- QT Interval Prolongation
- Allergic Reactions
- Elevated Liver Enzymes

Overdosage:

- **Severe QT Prolongation:** Increased risk of serious cardiac arrhythmias.
- **Hypotension:** Possible drop in blood pressure.
- **Seizures:** In rare cases, overdose may lead to seizures.

- Serotonin Syndrome: Symptoms may include agitation, confusion, rapid heartbeat, and muscle rigidity.

Treatment of overdose involves supportive care, monitoring cardiac function, and potentially using medications to manage symptoms. Immediate medical attention is necessary in cases of suspected overdose.

Route of Administration: Oral. To be swallowed as whole tablet with water.

Dosage: As directed by the physician.

Storage: Store protected from light and moisture, at a temperature not exceeding 30°C.

Presentation: It is available as 10x10 strips of tablets per box.

