

(Ondansetron 2mg/5ml syrup)

Each 5 ml Contains:

| Ondansetron Hydrochloride IP | 2 mg |
|------------------------------|------|
| Excipientsq.s. | |

Clinical Pharmacology:

Ondansetron: Ondansetron is a selective serotonin 5-HT3 receptor antagonist. It works by blocking the action of serotonin, a natural substance that can cause nausea and vomiting. It is primarily used in the prevention of nausea and vomiting associated with chemotherapy, radiotherapy, and surgery.

Indications:

- Prevention of nausea and vomiting associated with chemotherapy and radiotherapy.
- Prevention and treatment of postoperative nausea and vomiting.
- Treatment of nausea and vomiting due to other medical conditions.

Contraindications:

- Hypersensitivity to ondansetron or any of the excipients.
- Concomitant use with apomorphine due to the risk of profound hypotension and loss of consciousness.

Precautions and Warnings:

- In cases of hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving ondansetron.
- Ondansetron prolongs the QT interval in a dose-dependent manner. Caution should be exercised in patients with a history of prolonged QT syndrome or in those taking other medications that can prolong QT interval.
- Use of ondansetron may lead to serotonin syndrome, especially when used with other serotonergic drugs. Symptoms include agitation, hallucinations, tachycardia, and increased body temperature.
- Hepatic Impairment: In patients with severe hepatic impairment, the clearance of ondansetron is significantly reduced. The daily dose should not exceed 8 mg.

Drug Interactions:

- Apomorphine: Concomitant use is contraindicated due to the risk of severe hypotension.
- Serotonergic Drugs: Caution is advised when ondansetron is used with other serotonergic drugs (e.g., SSRIs, SNRIs) due to the risk of serotonin syndrome.
- QT-Prolonging Drugs: Caution should be taken when co-administered with drugs that prolong the QT interval, such as certain anti-arrhythmics, antipsychotics, and antibiotics.

Adverse Effects:

- Common Adverse Effects: Headache, fatigue, constipation, and dizziness.
- Serious Adverse Effects: QT prolongation, arrhythmias, bronchospasm, and anaphylactic reactions.

Overdosage:

Symptoms: Overdose of Ondansetron may result in symptoms such as visual disturbances, severe constipation, hypotension, and vasodilation.

Management: No specific antidote for Ondansetron overdose is known. Ondansetron is not removed by dialysis. Symptomatic and supportive therapy should be provided.

Route of Administration: Administer the prescribed dose of syrup by mouth. Shake well before use. Ensure the correct dose is administered using a dosing syringe or measuring cup.

SCHEDULE H PRESCRIPTION DRUG CAUTION:

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Dosage: As directed by a physician. The usual dosage for adults and pediatric patients will

vary based on the indication, weight, and clinical condition of the patient.

Storage: Store in a cool, dry place at a temperature below 30°C. Protect from light and moisture. Keep out of reach of children.

Presentation: Available as 60 ml bottles.



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