

Information For the User
Ondansetron HCL I.P. 8mg Injection

Ondotyle 8 Injection

Brand Name: Ondotyle 8 Injection

Composition:

Each ml contains:

Ondansetron Hydrochloride IP equivalent to Ondansetron 8 mg

Therapeutic Indication:

Indicated for the prevention and treatment of nausea and vomiting associated with chemotherapy, radiotherapy, and postoperative procedures

Helps in improving patient comfort and compliance during emetogenic therapy

Mechanism of Action:

Ondansetron is a selective 5-HT₃ receptor antagonist

It blocks serotonin receptors centrally in the chemoreceptor trigger zone and peripherally on vagal nerve terminals in the gastrointestinal tract

This inhibits the vomiting reflex mediated by serotonin release

Dosage & Administration:

Usual adult dose: 8 mg administered intravenously slowly over 2 to 5 minutes or as directed by the physician

For chemotherapy-induced nausea and vomiting, dose may be given 30 minutes before therapy

For postoperative nausea and vomiting, administer immediately before induction of anesthesia or postoperatively as required

Do not exceed recommended dose

Contraindications:

Hypersensitivity to Ondansetron or any component of the formulation

Concomitant use with apomorphine due to risk of severe hypotension and loss of consciousness

Warnings & Precautions:

Use with caution in patients with hepatic impairment or electrolyte imbalance

Monitor for signs of QT prolongation in patients with cardiac risk factors

Avoid rapid intravenous administration to prevent transient hypotension or bradycardia

Pregnancy and lactation use only if clearly needed and prescribed by a physician

Side Effects:

Common: headache, constipation, dizziness, fatigue

Less common: transient hypotension, flushing, mild elevation of liver enzymes

Rare: anaphylactic reactions, arrhythmias including QT prolongation, extrapyramidal symptoms

Storage:

Store in a cool dry place below 25°C

Protect from light and moisture

Keep out of reach of children

Packaging:

Ondotyle 8 Injection is available in 2 ml or 4 ml ampoules/ vials

Schedule:

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

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