NAUSETRON®

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about NAUSETRON
Each NAUSETRON tablet for oral administration contains ondansetron HCl dihydrate equivalent to 8 mg ondansetron with the following excipients: lactose monohydrate, pregelatinized maize starch, croscarmellose sodium and magnesium stearate.
Each 5 mL of NAUSETRON sugar free oral solution contains ondansetron HCl dihydrate equivalent to 4 mg ondansetron with the following excipients: citric acid, sodium benzoate, sodium citrate, sorbitol, strawberry liquid, and purified water.
Ondansetron is a selective antagonist of serotonin receptors of the 5-HT_3 type. It blocks the initiation of vomiting reflex.
NAUSETRON is indicated in the following conditions:
-Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy in adults.
-Prevention of post-operative nausea and vomiting (PONV) in adults.
-Management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥6 months.
The way to take NAUSETRON
Take NAUSETRON as directed by your physician. Do not discontinue the treatment or change the dosage prescribed without consulting your doctor.
The selection of dose regimen should be determined according to the emetogenic potential of cancer treatment:
-Emetogenic chemotherapy and radiotherapy in adults: 8 mg taken 1 to 2 hours before chemotherapy or radiation treatment, followed by 8 mg every 12 hours for a maximum of 5 days to protect against delayed or prolonged emesis.
-Highly emetogenic chemotherapy in adults: a single dose of up to 24 mg 1 to 2 hours before chemotherapy, may be used.
To protect against delayed or prolonged emesis after the first 24 hours, this drug may be continued for up to 5 days after a course of treatment. The recommended dose for oral administration is 8 mg to be taken twice daily.
-Chemotherapy-induced nausea and vomiting in children aged ≥6 months and adolescents:
The dose for CINV can be calculated based on body surface area (BSA) or weight; Weight-based dosing results in higher total daily doses compared to BSA-based dosing
Dosing by bodyweight:

Weight	**Day 1**	**Day 2-6**
≤10 kg	Up to 3 doses of 0.15 mg/kg IV every 4 hours	2 mg (2.5 mL) syrup every 12 hours
>10 kg	Up to 3 doses of 0.15 mg/kg IV every 4 hours	4 mg (5 mL) syrup or half a tablet every 12 hours

The intravenous dose must not exceed 8 mg.
The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32 mg.

-Prevention of PONV in adults: 16 mg one hour prior to anesthesia.
-In patients with severe hepatic impairment, a total daily dose of 8 mg should not be exceeded.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Contact your doctor if you miss a dose.

Contraindications

This drug is contraindicated in the following conditions:
- Hypersensitivity to any of the components
- Concomitant use with apomorphine

Precautions

- If hypersensitivity reactions occur, discontinue the treatment immediately.
- Respiratory events should be treated immediately.
- Avoid this drug in patients with congenital long QT syndrome. This drug should be administered with caution in patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias or patients taking other medicinal products that lead to QT prolongation or electrolyte abnormalities.
-Hypokalemia and hypomagnesemia must be corrected before taking this drug.
-An observation of the patient should be done in case of co-administration of other serotonergic drugs.
-Patients with signs of subacute intestinal obstruction should be monitored following the administration of this drug.
-This drug may mask occult bleeding in patients given ondansetron in adenotonsillar surgery for the prevention of nausea and vomiting; patients must be followed carefully.
-Pediatric patients receiving ondansetron with hepatotoxic chemotherapeutic agents should be monitored closely for impaired hepatic function.
-Inform your doctor before using this medication in case of pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
Concomitant use with apomorphine is contraindicated.
Serotonin syndrome has been described following the concomitant use of 5-HT3 receptor antagonists and other serotonergic drugs, including selective serotonin reuptake inhibitors and serotonin and noradrenaline reuptake inhibitors.
Caution should be used with phenytoin, carbamazepine, rifampicin and with medicines that prolong QT interval and/or cause electrolyte abnormalities.
Reduced analgesic efficacy of tramadol has been reported in patients also given ondansetron.

Adverse reactions

The most common reported adverse reactions include: headache, constipation, and flushing.
Other reported adverse reactions include: cardiovascular disorders, seizures, movements disorders, hypersensitivity reactions, hiccups, liver enzyme abnormalities.
Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

NAUSETRON, ondansetron 8 mg, pack of 10 tablets
NAUSETRON, ondansetron 4 mg/ 5mL, bottle of 100 mL with a dosing cup
NAUSETRON, ondansetron 4 mg/ 5mL, bottle of 60 mL with a dosing cup

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Manufactured by Mediphar Laboratories -Lebanon