

شراب

للمصناعات الدوائية - حلب - سوريا

Ondasetrin

SYRUP

Contraindications:

Each 5ml of syrup contains:
5mg ondansetron Hydrochloride dihydrate, equivalent to 4mg ondansetron
Hypersensitivity to any component of the preparation.
Concomitant use with apomorphine.

Side Effects:

Nervous system disorders:

-Very common: Headache

-Uncommon: Seizures, movement disorders (including extrapyramidal reactions such as dystonic reactions, oculogyric crisis and dyskinesia); observed without definitive evidence of persistent clinical sequelae

Cardiac disorders:

Uncommon: Arrhythmias, chest pain with or without ST segment depression, bradycardia.

Vascular disorders

-Common: Sensation of warmth or flushing

-Uncommon: Hypotension

Respiratory, thoracic and mediastinal disorders:

Uncommon: Hiccups

Gastrointestinal disorders:

Common: Constipation

Hepatobiliary disorders:

Uncommon: Asymptomatic increases in liver function tests. These events were observed commonly in patients receiving chemotherapy with cisplatin.

Warnings & Precautions:

-Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5HT₃ receptor antagonists.

-Respiratory events should be treated symptomatically and clinicians should pay particular attention to them as precursors of hypersensitivity reactions.

-Rarely, transient ECG changes including QT interval prolongation have been reported in patients receiving ondansetron. In addition, Ondansetron should be administered with caution to patients who have or may develop prolongation of QTc. These conditions include patients with electrolyte abnormalities, with congenital long QT syndrome, or patients taking other medicinal products that lead to QT prolongation. Therefore, caution should be exercised in patients with cardiac rhythm or conduction disturbances, in patients treated with antiarrhythmic agents or beta-adrenergic blocking agents and in patients with significant electrolyte disturbances.

-As ondansetron is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.

-In patients with adenotonsillar surgery prevention of nausea and vomiting with ondansetron may mask occult bleeding. Therefore, such patients should be followed carefully after ondansetron.

-Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Ondansetron.

Drug Interactions:

-Phenyltin, Carbamazepine and Rifampicin: In patients treated with potent inducers of CYP3A4 (i.e., phenyltin, carbamazepine, and rifampicin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.

-Tramadol: ondansetron may reduce the analgesic effect of tramadol.

-Use of ondansetron with QT prolonging drugs may result in additional QT prolongation.

-Concomitant use of ondansetron with cardiotoxic drugs (e.g., anthracyclines) may increase the risk of arrhythmias.

Women of childbearing potential:

Women of childbearing potential should consider the use of contraception.

Pregnancy:

Based on human experience from epidemiological studies, ondansetron is suspected to cause orofacial malformations when administered during the first trimester of pregnancy. So, ondansetron should not be used during the first trimester of pregnancy.

Lactation: It is recommended that mothers receiving ondansetron should not breast-feed their babies.

Dosage and Administration: Adults recommended dosage regimen for prevention of nausea and vomiting:

- The recommended dose for oral administration is 8 mg to be taken twice daily.

- For chemotherapy and radiotherapy: The recommended dose is 8 mg taken 1 to 2 hours before treatment, followed by 8 mg every 12 hours for maximum of 5 days.

-For highly emetogenic chemotherapy: a single dose of up to 24mg ondansetron taken with 12mg oral dexamethasone sodium phosphate, 1 to 2 hours before chemotherapy, may be used.

-To protect against delayed or prolonged emesis after the first 24 hours, oral or rectal treatment with Ondansetron should be continued for up to 5 days after a course of treatment. The recommended dose for oral administration is 8mg twice daily.

Paediatric Population:

Chemotherapy –induced nausea and vomiting CINV in children aged ≥6 months and adolescents:

The dose for CINV can be calculated based on body surface area (BSA) or weight – see below.

In paediatric clinical studies, ondansetron was given by IV infusion diluted in 25 to 50 mL of saline or other compatible infusion fluid and infused over not less than 15 minutes.

Weight-based dosing results in higher total daily doses compared to BSA-based dosing.

Ondansetron injection should be diluted in 5% dextrose or 0.9% sodium chloride or other compatible infusion fluid and infused intravenously over not less than 15 minutes. There are no data from controlled clinical trials on the use of ondansetron in the prevention of delayed or prolonged CINV.

There are no data from controlled clinical trials on the use of ondansetron for radiotherapy-induced nausea and vomiting in children.

Dosing by body surface area (BSA): Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 5 mg/m². The intravenous dose must not exceed 8mg.

Oral dosing can commence twelve hours later and may be continued for up to 5 days.

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

BSA-based dosing for Chemotherapy - Children aged ≥6 months and adolescents:

BSA	Day 1(a, b)	Days 2 – 6(b)
< 0.6m ²	5mg/m ² i.v. plus 2mg syrup after 12 hrs	2mg syrup every 12 hours
≥ 0.6 m ² to ≤ 1.2 m ²	5mg/m ² i.v. plus 4mg syrup or tablet after 12 hrs	4mg syrup or tablet every 12 hrs
>1.2m ²	5mg/m ² or 8mg IV plus 8mg syrup or tablet after 12 hrs	8mg syrup or tablet every 12 hours

a The intravenous dose must not exceed 8mg.

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

Dosing by bodyweight:

Weight-based dosing results in higher total daily doses compared to BSA-based dosing.

Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 0.15 mg/kg. The intravenous dose must not exceed 8 mg.

Two further intravenous doses may be given in 4-hourly intervals.

Oral dosing can commence twelve hours later and may be continued for up to 5 days

(Table 2). The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32mg.

Body Weight	Day 1(a, b)	Days 2 – 6(b)
≤ 10 kg	- As a single IV dose 0.15 mg/kg before chemotherapy start. - Tow further IV doses may be given in 4 hourly intervals.	2 mg syrup (equivalent to 2.5 ml of syrup) every 12 hours for up of 5 days
	- As a single IV dose 0.15 mg/kg before chemotherapy start. - Tow further IV doses may be given in 4 hourly intervals.	4 mg syrup (equivalent to 5 ml of syrup) every 12 hours for up of 5 days

a- The intravenous dose must not exceed 8mg

b- The total dose over 24 hours must not exceed adult dose of 32 mg.

Post operative nausea and vomiting (PONV):

Adults: For the prevention of PONV: Ondansetron can be administered orally or by intravenous or intramuscular injection.

For oral administration: 16mg one hour prior to anaesthesia.

For the treatment of established PONV: Intravenous or intramuscular administration is recommended.

Paediatric population: PONV in children aged ≥1 month and adolescents:

Oral formulation: No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; slow IV injection (not less than 30 seconds) is recommended for this purpose.

Injection: For prevention of PONV in paediatric patients having surgery performed under general anaesthesia, a single dose of ondansetron may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg either prior to, at or after induction of anaesthesia.

For the treatment of PONV after surgery in paediatric patients having surgery performed under general anaesthesia, a single dose of Ondansetron may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg.

There are no data on the use of ondansetron in the treatment of PONV in children below 2 years of age.

Elderly: Ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

For both indications. Patients with Renal impairment:

No alteration of daily dosage or frequency of dosing, or route of administration are required.

Patients with Hepatic impairment: Clearance of Ondansetron is significantly reduced and serum half life significantly prolonged in subjects with moderate or severe impairment of hepatic function.

In such patients a total daily dose of 8mg should not be exceeded.

Overdosage: Symptoms and Signs: Manifestations that have been reported include visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second-degree AV block.

Treatment: There is no specific antidote for ondansetron, therefore in all cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate. The use of ipecacuanha to treat overdose with ondansetron is not recommended, as patients are unlikely to respond due to the anti-emetic action of ondansetron itself.

Storage conditions: Store at a temperature below 25°C, away from heat and out of reach of children.

How supplied: Opaque glass bottle with a capacity of 100 ml.

THIS IS A MEDICAMENT

A medicament is a Product but Unlike any Other Products
A medicament is a Product Which Affects Your health, and its Consumption Contrary to Instructions is Dangerous for you.
Follow Strictly the Doctors' Prescription, the Method of use and the Instructions of the Pharmacist who Sold the Medicament. The Doctor and the Pharmacist are Experts in Medicine, its Benefits and Risks.
Do not by Yourself Interrupt the Period of Treatment Prescribed for you.
Do not Repeat the Same Prescription Without Consulting your Doctor.

Keep Medicaments out of Reach of children
(Council of Arab Health Ministers) (Arab Pharmacists Association)

AMEEN PHARMA
Pharmaceutical Industry
Aleppo-Syria

Sy541-L