

Vekonex

(Ondansetron)

ویکونیکس
(اونڈنسترون)

COMPOSITION

Vekonex 8mg Tablet

Each film coated tablet contains:

Ondansetron as Hydrochloride Dihydrate 8mg

Product Specs.: U.S.P.

Vekonex Orodispersible 8mg Tablet

Each Orodispersible tablet contains:

Ondansetron 8mg

Product Specs.: U.S.P.

Vekonex 4mg/5mL Syrup

Each 5mL contains:

Ondansetron as Hydrochloride Dihydrate 4mg

Product Specs.: U.S.P.

Vekonex 4mg/2mL Injection

Each mL contains:

Ondansetron as Hydrochloride Dihydrate 2mg

Product Specs.: U.S.P.

Vekonex 8mg/4mL Injection

Each mL contains:

Ondansetron as Hydrochloride Dihydrate 2mg

Product Specs.: U.S.P.

MECHANISM OF ACTION

Ondansetron is a selective 5-HT₃ receptor antagonist. Serotonin receptors of the 5-HT₃ type are present both peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. It is not certain whether ondansetron's antiemetic action is mediated centrally, peripherally, or in both sites. However, cytotoxic chemotherapy appears to be associated with release of serotonin from the enterochromaffin cells of the small intestine. In humans, urinary 5-hydroxyindoleacetic acid (5-HIAA) excretion increases after cisplatin administration in parallel with the onset of emesis. The released serotonin may stimulate the vagal afferents through the 5-HT₃ receptors and initiate the vomiting reflex.

PHARMACOKINETICS

Absorption: Ondansetron is absorbed from the gastrointestinal tract and undergoes some first-pass metabolism. Mean bioavailability in healthy subjects, following administration of a single 8-mg tablet, is approximately 56%.

Ondansetron systemic exposure does not increase proportionately to dose. The AUC from a 16-mg tablet was 24% greater than predicted from an 8-mg tablet dose. This may reflect some reduction of first-pass metabolism at higher oral doses.

Food Effects: Bioavailability is also slightly enhanced by the presence of food.

Distribution: Plasma protein binding of ondansetron as measured in vitro was 70% to 76% over the concentration range of 10 to 500 ng/mL. Circulating drug also distributes into erythrocytes.

Metabolism: Ondansetron is extensively metabolized in humans. The metabolites are observed in the urine.

Excretion: In adult cancer patients, the mean ondansetron elimination half-life was 4.0 hours, and there was no difference in the multidose pharmacokinetics over a 4-day period.

Specific Populations

Geriatric Population: A reduction in clearance and increase in elimination half-life are seen in patients older than 75 years compared to younger subjects.

INDICATIONS

Vekonex is indicated for the prevention of nausea and vomiting associated with:

- Highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m².
- Initial and repeat courses of moderately emetogenic cancer chemotherapy.
- Radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
- Prevention of postoperative nausea and/or vomiting.

DOSAGE AND ADMINISTRATION

Adult Recommended Dosage Regimen for Prevention of Nausea and Vomiting:

Indication	Tab. Vekonex Dosage Regimen
Highly Emetogenic Cancer Chemotherapy	A single 24-mg dose administered 30 minutes before the start of single-day highly emetogenic chemotherapy, including cisplatin greater than or equal to 50 mg/m ² .
Moderately Emetogenic Cancer Chemotherapy	8 mg administered 30 minutes before the start of chemotherapy, with a subsequent 8-mg dose 8 hours after the first dose. Then administer 8 mg twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.
Radiotherapy	<i>For total body irradiation:</i> 8 mg administered 1 to 2 hours before each fraction of radiotherapy each day. <i>For single high-dose fraction radiotherapy to the abdomen:</i> 8 mg administered 1 to 2 hours before radiotherapy, with subsequent 8-mg doses every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy. <i>For daily fractionated radiotherapy to the abdomen:</i> 8 mg administered 1 to 2 hours before radiotherapy, with subsequent 8-mg doses every 8 hours after the first dose for each day radiotherapy is given.
Postoperative	16 mg administered 1 hour before induction of anesthesia.

Administration Instructions for Vekonex Orodispersible Tablets:

- Handle tablet with dry hands.
- Immediately place the tablet on top of the tongue where it will dissolve in seconds, then swallow with saliva.
- Administration with liquid is not necessary.

Pediatric Recommended Dosage Regimen for Prevention of Nausea and Vomiting:

Indication	Syp. Vekonex Dosage Regimen
Moderately Emetogenic Cancer Chemotherapy	<i>12 to 17 years of age:</i> 8 mg administered 30 minutes before the start of chemotherapy, with a subsequent 8-mg dose 4 and 8 hours after the first dose. Then administer 8 mg three times a day for 1 to 2 days after completion of chemotherapy. <i>4 to 11 years of age:</i> 4 mg administered 30 minutes before the start of chemotherapy, with a subsequent 4-mg dose 4 and 8 hours after the first dose. Then administer 4 mg three times a day for 1 to 2 days after completion of chemotherapy.

Adult and Pediatric Recommended Dosage Regimen for Prevention of Nausea and Vomiting:

Indication	Inj. Vekonex Dosage Regimen
Nausea and Vomiting Associated with Emetogenic Chemotherapy	● Dilution of Ondansetron Injection in 50 mL of 5% Dextrose Injection or 0.9% Sodium Chloride Injection is required before administration to adult and pediatric patients. ● Adults and pediatric patients 6 months of age and older: The recommended dosage is 0.15 mg/kg per dose for 3 doses (maximum of 16 mg per dose), infused intravenously over 15 minutes. ● Administer the first dose 30 minutes before the start of chemotherapy and subsequent doses 4 and 8 hours after the first dose.
Prevention of Postoperative Nausea and/or Vomiting	● Dilution of Ondansetron Injection is not required before administration to adult and pediatric patients. ● The recommended adult dose is 4 mg administered as an IV injection over 2 to 5 minutes, either before anesthesia induction or postoperatively if needed within 2 hours of surgery. ● A single 4 mg intramuscular (IM) injection is also an option for adults. ● For pediatric patients (1 month to 12 years), the dose is 0.1 mg/kg for those weighing 40 kg or less, and 4 mg for those over 40 kg, given immediately before or after anesthesia induction.

Dosage in Hepatic Impairment

In patients with severe hepatic impairment, do not exceed a total daily dose of 8 mg. **Renal Impairment:** Although plasma clearance is reduced in patients with severe renal impairment (creatinine clearance < 30 mL/min), no dosage adjustment is recommended.

Pediatric Use: The safety and effectiveness of orally administered ondansetron have been established in pediatric patients 4 years and older for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

Little information is available about the use of ondansetron injection in pediatric surgical patients younger than 1 month. Little information is available about the use of ondansetron injection in pediatric cancer patients younger than 6 months.

ADVERSE REACTIONS

The most common adverse reactions are headache, fever, malaise/fatigue, constipation, diarrhea and hypoxia.

DRUG INTERACTIONS

Serotonergic Drugs: Monitor for the emergence of serotonin syndrome. If symptoms occur, discontinue ondansetron and initiate supportive treatment.

Drugs Affecting Cytochrome P-450 Enzymes: No dosage adjustment for ondansetron is recommended for patients on these drugs.

Tramadol: Monitor patients to ensure adequate pain control when ondansetron is administered with tramadol. **Chemotherapy:** Carmustine, etoposide, and cisplatin do not affect the pharmacokinetics of ondansetron. In a crossover trial in 76 pediatric patients, intravenous ondansetron did not increase systemic concentrations of high-dose methotrexate.

Alfentanil and Atracurium: Ondansetron does not alter the respiratory depressant effects produced by alfentanil or the degree of neuromuscular blockade produced by atracurium. Interactions with general or local anesthetics have not been studied.

Apomorphine: Based on reports of profound hypotension and loss of consciousness when apomorphine was administered with ondansetron, the concomitant use of apomorphine with ondansetron is contraindicated.

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions including anaphylaxis and bronchospasm: Discontinue if suspected. Monitor and treat promptly per standard of care until signs and symptoms resolve.

QT interval prolongation and Torsade de Pointes: Avoid in patients with congenital long QT syndrome; monitor with electrocardiograms (ECGs) if concomitant electrolyte abnormalities, cardiac failure or arrhythmias, or use of other QT prolonging drugs.

Serotonin syndrome: Reported with 5-HT₃ receptor antagonists alone but particularly with concomitant use of serotonergic drugs. If such symptoms occur, discontinue Ondansetron and initiate supportive treatment. If concomitant use with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome.

Masking of progressive ileus and/or gastric distention following abdominal surgery or chemotherapy-induced nausea and vomiting: Monitor for decreased bowel activity, particularly in patients with risk factors for gastrointestinal obstruction.

Pregnancy: Pregnancy Category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether ondansetron is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ondansetron is administered to a nursing woman.

CONTRAINDICATIONS

- Ondansetron is contraindicated for patients known to have hypersensitivity to this product or any of its components.
- The concomitant use of apomorphine with ondansetron is contraindicated.

OVERDOSAGE

There is no specific antidote for ondansetron overdose. Patients should be managed with appropriate supportive therapy.

PRESENTATION

Vekonex 8mg Tablets:	1 x 10's/pack
Vekonex Orodispersible 8mg Tablets:	1 x 10's/pack
Vekonex 4mg/5mL Syrup:	50mL bottle
Vekonex 4mg/2mL Injection:	2mL x 1 ampoule/pack
Vekonex 8mg/4mL Injection:	4mL x 1 ampoule/pack

DOSAGE

As directed by the physician.

INSTRUCTIONS

Store below 30°C.
Protect from light, heat and moisture.
Keep out of the reach of children.
To be sold on the prescription of registered medical practitioner only.

Detailed prescribing information is available on request.

Manufactured by:
Asian Continental (Pvt.) Ltd.
D-32, S.I.T.E. II, Super Highway,
Karachi-Pakistan.

Manufactured by:
Wimits Pharmaceuticals (Pvt.) Ltd.
129, Sunder Industrial Estate, Lahore.



An ISO Certified Company

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
دوا کو 30°C سے کم درجہ حرارت پر رکھیں۔
روشنی، گرمی اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کی جائے۔