

VOMIDAL

Tablets & Syrup



Composition:

Tablets: Each VOMIDAL film coated tablet contains: ondansetron 8 mg (as hydrochloride dihydrate).

Syrup: Each VOMIDAL 5ml of syrup contains: ondansetron 4 mg (as hydrochloride dihydrate).

Mechanism of Action: VOMIDAL is a potent, highly selective 5HT₃ receptor-antagonist. The effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of 5HT₃ receptors on neurons located both in the peripheral and central nervous system.

Pharmacokinetics: Following oral administration, ondansetron is completely absorbed from the gastrointestinal tract and undergoes first pass metabolism (bioavailability is about 60%). Peak plasma concentrations are attained approximately 1.5 hours after an 8 mg dose. The protein binding of ondansetron is 70-76%. Ondansetron is cleared from the systemic circulation predominantly by hepatic metabolism through multiple enzymatic pathways. Less than 5% of the absorbed dose is excreted unchanged in the urine.

Indications: Vomidal is indicated for the management of:

- Chemotherapy and Radiotherapy induced nausea and vomiting.
- Post-operative nausea and vomiting (PONV).

Contraindications:

- Hypersensitivity to the ondansetron, to other selective 5-HT₃ receptor antagonists.
- Concomitant use with apomorphine.

Warnings & Precautions:

- Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5HT₃ receptor antagonists.
- VOMIDAL should be used with caution in patients who may develop prolongation of QTc.
- Hypokalemia and hypomagnesemia should be corrected prior to ondansetron administration.
- Pediatric patients receiving ondansetron with hepatotoxic chemotherapeutic agents should be monitored closely for impaired hepatic function.
- As ondansetron is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.

Pregnancy & Lactation:

Pregnancy: Pregnancy Category B, special care should be taken during the first trimester of pregnancy.

Lactation: It is recommended that the mother does not breast-feed her baby while she is using ondansetron treatment.

Drug Interactions:

- Since ondansetron is metabolized by the hepatic cytochrome enzymes of drug metabolism, these enzymes may affect ondansetron excretion and thus alter the half-life of the drug, depending on Data available It is not recommended to adjust the dose of ondansetron in patients taking these medicines.
- Caution should be exercised when ondansetron is co-administered with drugs that prolong the QT interval and/or cause electrolyte abnormalities.
- Serotonergic Drugs (e.g., SSRIs and SNRIs): serotonin syndrome following the concomitant use of ondansetron and other serotonergic drugs have been reported.
- **Apomorphine:** concomitant use with apomorphine is contraindicated.
- **Phenytoin, Carbamazepine and Rifampicin:** In patients treated with potent inducers of CYP3A4 (i.e. phenytoin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.
- **Tramadol:** ondansetron may reduce the analgesic effect of tramadol.

Side Effects:

Common: Headache, sensation of warmth or flushing, constipation.

Uncommon and Rare: hypersensitivity reactions, Seizures, movement disorders, QTc prolongation, hypotension, hiccups, asymptomatic increases in liver function tests.

Dosage and Administration:

Adults: 8mg 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.

The recommended dose for oral administration is 8 mg twice daily.

Paediatric Population: Ondansetron hydrochloride should be administered immediately before chemotherapy as a single intravenous dose of 0.15 mg/kg. The single 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. The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32 mg.

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

Weight	Day 1 ^(a)	Days 2-6 ^(b)
≤ 10 Kg	Up to 3 doses of 0.15mg/kg iv every 4 hrs	2 mg syrup every 12 hrs
>10 Kg	Up to 3 doses of 0.15mg/kg iv every 4 hrs	4 mg syrup or tablet every 12 hrs

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 32 mg.

Post-operative nausea and vomiting (PONV) in adults: For oral administration: 16 mg one hour prior to anesthesia.

Patients with hepatic Impairment: Clearance of ondansetron hydrochloride is significantly reduced and serum half-life significantly prolonged. In such patients a total daily dose of 8mg should not be exceeded.

Overdose:

Symptoms: There is limited experience of ondansetron overdose. In the majority of cases, symptoms were similar to those already reported in patients receiving recommended doses. ECG monitoring is recommended in cases of overdose.

Treatment: There is no specific antidote for ondansetron, therefore symptomatic and supportive therapy should be given as appropriate.

Storage:

Store in a dry place at a temperature not exceeding 25°C and protect from light.

Packaging:

Tablets: Each VOMIDAL carton contains 10 film coated tablets in a blister strip.

Syrup: Each VOMIDAL carton contains a opaque bottle of 100 ml.

- A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
- KEEP THE MEDICATIONS OUT OF REACH OF CHILDREN.
- Council of Arab Health Ministers & Union of Arab Pharmacists

Revapharmaceutical Industry - Syria

