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StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-.

# Ondansetron

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Last Update: February 15, 2023.

## Continuing Education Activity

Ondansetron is one of the medications most commonly used for the empiric treatment of nausea and vomiting. Ondansetron has excellent utility as an antiemetic drug, and it is effective against nausea and vomiting of various etiologies. Common uses of ondansetron include the prevention of chemotherapy-induced and radiation-induced nausea and vomiting, the prevention of postoperative nausea and vomiting, and off-label use for the prevention of nausea and vomiting associated with pregnancy. However, it is not effective for motion sickness-induced nausea. This activity will cover the mechanism of action, pharmacology, adverse event profiles, eligible patient populations, contraindications, and monitoring. It also highlights the interprofessional team's role in managing patients needing ondansetron therapy.

**Objectives:**

- Identify the antiemetic mechanism of action of ondansetron.
- Outline the approved and off-label indications for using ondansetron.
- Summarize the adverse event profile of ondansetron.
- Review the importance of improving care coordination among the interprofessional team to enhance the delivery of care for patients who can benefit from therapy with ondansetron.

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## Indications

Nausea and vomiting are common complaints seen by emergency department physicians and primary care clinicians daily.[1] Ondansetron is on the World Health Organization's (WHO) List of Essential Medicines, a list of medications considered effective and safe in meeting the essential needs of a health care system. Other antiemetics listed with ondansetron include dexamethasone and metoclopramide. In 2006 (the last year of its patent), the brand-name version of ondansetron was the 20th highest-selling brand-name drug in the United States, and its popularity continues today. Ondansetron has widespread utility as an antiemetic drug and is effective against nausea and vomiting of various etiologies.

The FDA-approved indications include the prevention of chemotherapy-induced nausea and vomiting (CINV), radiation-induced nausea and vomiting, and postoperative nausea and vomiting (PONV).[2] It is considered first-line therapy for the treatment of chemotherapy-induced and radiation-induced nausea and vomiting.[3][4]

Off-label use for the prevention of nausea and vomiting associated with pregnancy. Ondansetron has minimal efficacy in treating nausea and vomiting associated with motion sickness, which distinct neural centers and pathophysiological mechanisms mediate. There is limited data available from pediatric populations. Ondansetron is used in pediatric populations for the acute treatment of cyclic vomiting syndrome; however, there is limited evidence on its efficacy.

[5] Ondansetron is used off-label for severe refractory diarrhea associated with neuroendocrine tumors (carcinoid syndrome).[6]

## Mechanism of Action

Ondansetron is a selective 5-HT3 serotonin-receptor antagonist used for its antiemetic properties. It is 1 of the 4 FDA-approved 5-HT3 serotonin-receptor antagonists used to combat nausea and vomiting, including granisetron, dolasetron, and the second-generation drug, palonosetron.[7]

Ondansetron acts both centrally and peripherally to prevent and treat nausea and vomiting. Central effects are mediated by the antagonism of 5-HT3 serotonin receptors in the area postrema. The area postrema, located on the floor of the 4th ventricle, contains the "chemoreceptor trigger zone." This zone detects neurotransmitters such as serotonin, toxins, and other signals and mediates the sensation of nausea and subsequent vomiting. Ondansetron also exerts peripheral effects by acting on the vagus nerve. It acts on 5-HT3 receptors present at vagus nerve terminals. The vagus nerve can detect triggers of nausea and vomiting in the gastrointestinal tract, such as gastric irritants. It forms synapses within the nucleus tractus solitarius of the brainstem, another region important in vomiting. The peripheral actions of ondansetron are thought to be the predominant mechanism for its antiemetic effects.[8][9]

**Pharmacokinetics**

**Absorption:** Ondansetron is rapidly absorbed from the GI tract, with a peak plasma concentration (Tmax) of approximately 1.5 hours after an 8 mg single oral dose. The absolute bioavailability of ondansetron after oral administration is approximately 60%(50%-70%). The lower bioavailability is attributed to first-pass metabolism. The systemic bioavailability of ondansetron increases nonlinearly with doses of 8, 16, 32, and 64 mg due to saturation of first-pass metabolism. The bioavailability of ondansetron is significantly higher in patients with cancer (85% to 87%) than in healthy individuals (50%-70%), possibly due to alterations in metabolism.

**Distribution**: Ondansetron and its metabolites are extensively distributed in tissues. The apparent volume of distribution(Vd) at a steady state is approximately 1.8 L/kg. Ondansetron crosses the blood-brain barrier to a lesser extent, with the CSF concentration only about 10%-15% of the plasma concentration in human volunteers. Adenosine-binding cassette subfamily B member 1 (ABCB1) is a drug efflux transporter that transports ondansetron across the blood-brain barrier, thereby limiting its accumulation in the CNS. In patients with reduced ABCB1 activity, the brain concentration of ondansetron increases, thereby improving efficacy.[10]

**Metabolism:** The liver is the primary site of metabolism. The primary metabolic process is oxidation. 8-hydroxy ondansetron represents the major metabolite (40%), followed by 7-hydroxy ondansetron (< 20%) and 6-hydroxy ondansetron (<5%). Minor metabolism also occurs via N-demethylation, yielding N-demethyl ondansetron. The active metabolite of ondansetron is 8-hydroxy ondansetron, which is rapidly metabolized to glucuronide and sulfate conjugates in the liver, resulting in low blood concentrations and, thus, a very small contribution to ondansetron's antiemetic activity. Cytochrome P-450 enzymes, including CYP1A2, CYP2D6, and CYP3A4, are involved in the metabolism of ondansetron. In humans, CYP1A1/2 plays the most crucial role, while CYP2D6 plays a minor role in the metabolism of ondansetron. The role of CYP3A4 is important at higher ondansetron concentrations.[11]

**Excretion:** Hepatic metabolism accounts for nearly 95% of ondansetron clearance, and less than 5% is excreted unchanged in the urine. The clearance and elimination half-lives of ondansetron vary with age. The elimination half-life after an 8 mg oral or intravenous dose is approximately 3-4 h in adults, but on average, it is 5.5 hours in the elderly. Clearance ranges from 0.381 L/h/kg to 0.262 L/h/kg, depending on age. In adults, clearance is 0.351 5L/h/kg. The clearance per body

weight is higher in younger children. However, clearance is reduced in infants due to an underdeveloped cytochrome P450 enzyme system.[12]

## Administration

Routes of administration include oral, intramuscular, and intravenous. Oral formulations are available as dissolving tablets and soluble films. Ondansetron tablets should be administered 1 to 2 hours before radiotherapy, 30 minutes before chemotherapy, and an hour before anesthesia induction. Oral and intravenous formulations have been shown to have similar efficacy for treating emetogenic chemotherapy.

Dosing varies depending on the route of administration and the etiology. However, 16 mg per dose intravenously is the maximum recommended single dose due to the risk for QTc prolongation and arrhythmias. Standard dosing to prevent postoperative nausea and vomiting includes 8 mg every 12 hours orally or 4 mg given intravenously. No dosage adjustments are necessary for intravenous or oral administration in patients with renal impairment. The same holds for patients with mild to moderate hepatic impairment, but the maximum daily dosing is reduced to 8 mg intravenous or 8 mg orally in patients with severe hepatic impairment. Pediatric dosing is weight-based at 0.15 mg/kg per dose, with a maximum of 16 mg per dose.

**Use in Specific Patient Populations**

**Patients with Hepatic Impairment:** No dose adjustments of ondansetron are necessary for mild to moderate hepatic impairment. In patients with severe hepatic impairment, clearance of ondansetron is reduced; the volume of distribution and the plasma half-life are increased. Consequently, ondansetron should be used with caution, and the maximum recommended daily intravenous dose is reduced to 8 mg.[11]

**Patients with Renal Impairment:** No dosage adjustments are necessary for intravenous or oral administration.[11]

**Pregnancy Considerations:** Ondansetron is a former FDA “Pregnancy Category B” drug. It should only be used when other medications have been trialed and failed to treat pregnancy-associated nausea, vomiting, and hyperemesis gravidarum.[8] According to ACOG(The American College of Obstetricians and Gynecologists) guidelines, pyridoxine alone or combined with doxylamine is the preferred pharmacological therapy for nausea and vomiting. However, in refractory cases with persistent symptoms, ondansetron, 4 mg orally every 8 hours, may be considered(if there is no dehydration).[13] A possible association between first-trimester ondansetron use and cleft palate has been reported. Electrolyte and electrocardiogram monitoring are suggested in patients treated with ondansetron who have risk factors for arrhythmia, such as a family history of prolonged QT interval, heart failure, and electrolyte disturbances.[14] Recommendations for pregnant women with gynecological cancer suggest that 5-HT3 antagonists (including ondansetron ) can be used as supportive medication.[15]

**Breastfeeding Considerations:** In a pharmacokinetic study, the relative infant exposure to ondansetron is less.[16] Ondansetron is commonly used for nausea during and after a cesarean section, usually in doses of 4 to 8 mg intravenously. Using ondansetron during cesarean section does not affect the onset of breastfeeding. No adverse drug reactions have been reported in infants. Additionally, ondansetron is indicated for use in infants as young as 1 month. No specific precautions are required.[17]

## Adverse Effects

The most commonly reported side effects (occurring in more than 10% of adults) include headaches, fatigue, dry mouth, malaise, and constipation. Some less common effects range from central nervous system (CNS) manifestations, such as drowsiness and sedation, to local injection site reactions and pruritus.[18][19] A transient increase in liver function tests has also been

reported. The pattern of liver enzyme elevation is normally hepatocellular, with rare cases of clinically apparent acute liver injury or jaundice.[20]

Although typically clinically insignificant, EKG interval changes, such as QTc prolongation, can be observed. These changes typically occur within 1 to 2 hours after administration and return to baseline within 24 hours. As with any medication that causes QTc elongation, there is a concern for Torsade de Pointes and other arrhythmias.[21] Intravenous administration has a higher risk for arrhythmias; consequently, the FDA does not recommend a single dose greater than 16 mg intravenous.[22] Isolated cases of sinus bradycardia and asystole have also been reported.[23] Cases of intestinal obstruction due to impaired gut motility have been reported.[24] Stevens-Johnson syndrome has been reported in patients with multiple comorbidities.[25]

**Drug-Drug Interactions**

Concurrent administration of pimozide with ondansetron should be avoided due to the risk of QTc prolongation.[26] Amiodarone may also prolong the QTc interval; hence, administration with ondansetron requires monitoring.[27] There is a risk of serotonin syndrome when taking ondansetron in conjunction with other serotonergic medications.[28][26]

## Contraindications

Ondansetron is contraindicated in patients with hypersensitivity to the drug or any of its components.[29] Severe hypersensitivity reactions, including anaphylaxis, have been reported.[30][31] Ondansetron is also contraindicated in patients currently taking apomorphine. Concomitant use of ondansetron and apomorphine can lead to profound hypotension and loss of consciousness, with ondansetron enhancing the hypotensive effects of apomorphine.[32] Patients with phenylketonuria (PKU) should be cautious, as the dissolving tablet formulation can contain phenylalanine, leading to irreversible neurological damage in PKU patients.[33]

## Monitoring

Due to the potential for dose-dependent QTc interval elongation, the FDA recommends EKG monitoring along with potassium and magnesium in susceptible populations, such as the elderly or other at-risk groups. These at-risk groups include patients with electrolyte abnormalities such as hypokalemia, hypomagnesemia, heart failure, bradyarrhythmias, or patients on other medications that may prolong the QTc interval.[22][34]

Pregnant patients should be monitored for adverse fetal outcomes associated with ondansetron therapy.[35][36][37] Current evidence does not support routine EKG and electrolyte monitoring for ondansetron in the absence of known risk factors. Monitoring should be done in high-risk patients receiving ondansetron intravenously.[23][35]

## Toxicity

There is no known antidote to ondansetron, and supportive measures are used for overdose. A case report describes an ondansetron overdose in an infant presenting with seizures, QTc prolongation, hepatotoxicity, and serotonin syndrome. The patient required endotracheal intubation, supportive care, and lorazepam for seizures.[38]

## Enhancing Healthcare Team Outcomes

Ondansetron is a widely prescribed medication for nausea and vomiting from various causes. The drug is relatively safe, but prescribers need to monitor the drug in specific populations. Given the potential for dose-dependent QTc interval prolongation, clinicians should monitor electrocardiogram, potassium, and magnesium levels in susceptible populations. It includes the elderly or patients with electrolyte abnormalities such as hypokalemia, hypomagnesemia, heart failure, bradyarrhythmias, or patients on other medications that may prolong the QTc interval.

Current evidence does not support pre-screening this population before administering ondansetron to patients without any of the above risk factors.

An interprofessional team approach is critical for diagnosing and managing symptoms, treating patients with nausea and vomiting, and managing treatment-related adverse effects. Clinicians usually prescribe ondansetron for labeled indications. Oncologist consultation is necessary for CINV. Pharmacists should ensure appropriate dosing, perform medication reconciliation, and consult prescribers regarding any concerns. Nursing staff should monitor patients receiving medication and inform clinicians of any observed side effects. Emergency department physicians should rapidly stabilize the patient in case of an arrhythmia. Severe cases may require consultation with an intensivist and MICU/IMC-level care. Medical toxicologist consultation may become necessary in an overdose. If the overdose is intentional, psychiatric consultation is essential. An interprofessional team approach would maximize efficacy and minimize potential adverse drug reactions in patients requiring ondansetron, resulting in improved patient outcomes. A prospective study involving 789 patients demonstrated that an interprofessional team approach among clinicians, residents, clinical pharmacists, and oncologists reduced potential medication errors, eventually enhancing patient safety.

## Review Questions

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**Disclosure:** Alexandria Griddine declares no relevant financial relationships with ineligible companies.

**Disclosure:** Jeffrey Bush declares no relevant financial relationships with ineligible companies.

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