Taj Pharmaceuticals Ltd.

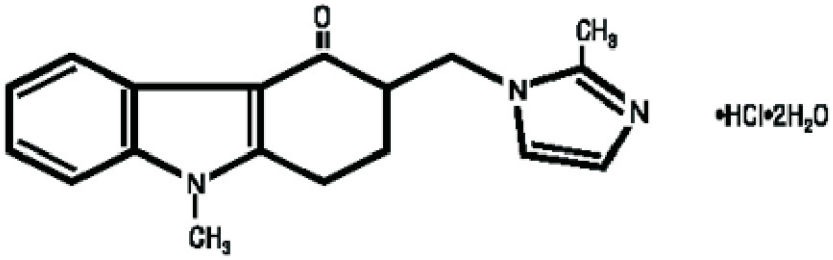
Ondansetron Base

CAS No. : 116002-70-1

CAS number 116002-70-1
ATC code A04AA01
PubChem 4595
DrugBank APRD00481
ChemSpider 4434

Chemical data

Formula C18H19N3O
Mol. mass 325.9 g/mol
SMILES eMolecules & PubChem



Pharmacokinetic data

Bioavailability ~60%
Protein binding 70%-76%
Metabolism Hepatic (CYP3A4, CYP1A2, CYP2D6)
Half life 5.7 hours
ondansetron hydrochloride (HCl), the racemic form of ondansetron and a selective blocking agent of the serotonin 5-HT3 receptor type. Chemically it is (±) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1- yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate.

The empirical formula is C18H19N3O•HCl•2H2O, representing a molecular weight of 365.9.
Ondansetron HCl is a white to off-white powder that is soluble in water and normal saline.

DOSAGE

This medication may be taken with or without food. It may also be taken with antacids. The first dose is usually taken 30 minutes before chemotherapy. Take further doses as directed, usually for 1-2 days after completion of chemotherapy. Other medical conditions and procedures require different dosing schedules. Follow your doctor's orders carefully.Ondansetron can be taken with or without food.Take the ondansetron regular tablet with a full glass of water.

To take ondansetron orally disintegrating tablet

*Keep the tablet in its blister pack until you are ready to take the medicine. Open the package and peel back the foil from the tablet blister. Do not push a tablet through the foil or you may damage the tablet.
*Using dry hands, remove the tablet and place it in your mouth. It will begin to dissolve right away.
*Do not swallow the tablet whole. Allow it to dissolve in your mouth without chewing.
*Swallow several times as the tablet dissolves. If desired, you may drink liquid to help swallow the dissolved tablet.

Measure the liquid form of ondansetron with a special dose-measuring spoon or cup, not a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist for one.
Store ondansetron at room temperature away from moisture and heat.

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throatserious side effects:

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*blurred vision or temporary blindness;
*fever;
*slow heart rate, trouble breathing;
*anxiety, agitation, shivering;
*feeling light-headed, fainting; or
*urinating less than usual or not at all.

Less serious side effects may include:

*diarrhea or constipation;
*weakness or tired feeling;
*headache;
*dizziness or drowsiness;

PRECAUTIONS

Before taking ondansetron,

* tell your doctor and pharmacist if you are allergic to ondansetron, alosetron , dolasetron , granisetron , palonosetron , any other medications, or any of the ingredients in ondansetron tablets or liquid. Ask your pharmacist for a list of the ingredients.
* tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention tramadol . Your doctor may need to change the doses of your medications or monitor you more carefully for side effects.
* tell your doctor if you have or have ever had liver disease.
* tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking ondansetron, call your doctor.
* if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent mental retardation), you should know that the orally disintegrating tablets contain aspartame that forms phenylalanine.
Tell your doctor your medical history, especially of: stomach/intestinal problems (e.g., distension), liver disease, any allergies. Limit alcohol intake, as it may intensify drug side effects. Caution performing tasks requiring alertness (e.g., driving) until you know how this medication affects you. Tell your doctor if you are pregnant before using this medication. It is not known if this drug is excreted into breast milk. Consult your doctor before breast-feeding.

INTERACTION

Before receiving ondansetron, tell your doctor if you are using any of the following drugs:

*phenytoin (Dilantin), phenobarbital (Luminal);
*carbamazepine (Carbatrol, Tegretol);
*tramadol (Ultram); or
*rifampin (Rifadin, Rimactane, Rifater).
Ondansetron does not itself appear to induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system of the liverBecause ondansetron is metabolized by hepatic cytochrome P-450 drug-metabolizing enzymes (CYP3A4, CYP2D6, CYP1A2), inducers or inhibitors of these enzymes may change the clearance and, hence, the half-life of ondansetron. On the basis of limited available data, no dosage adjustment is recommended for patients on these drugs.Tramadol:

Although no pharmacokinetic drug interaction between ondansetron and tramadol has been observed, data from 2 small studies indicate that ondansetron may be associated with an increase in patient controlled administration of tramadol

Chemotherapy: Tumor response to chemotherapy in the P 388 mouse leukemia model is not affected by ondansetron. In humans, carmustine, etoposide, and cisplatin do not affect the pharmacokinetics of ondansetron.In a crossover study in 76 pediatric patients, I.V. ondansetron did not increase blood levels of high- dose methotrexate.

DRUG DESCRIPTION

Ondansetron Base is a white to off-white powder that is soluble in water and normal saline.Each 1 mL of aqueous solution in the 2-mL single-dose vial contains 2 mg of ondansetron as the hydrochloride dihydrate; 9.0 mg of sodium chloride, USP; and 0.5 mg of citric acid monohydrate, USP and 0.25 mg of sodium citrate dihydrate, USP as buffers in Water for Injection, USP. Each 1 mL of aqueous solution in the 20-mL multidose vial contains 2 mg of ondansetron as the hydrochloride dihydrate; 8.3 mg of sodium chloride, USP; 0.5 mg of citric acid monohydrate, USP and 0.25 mg of sodium citrate dihydrate, USP as buffers; and 1.2 mg of methylparaben, NF and 0.15 mg of propylparaben, NF as preservatives in Water for Injection, USP.This medication is used to prevent nausea and vomiting caused by cancer chemotherapy or after surgery. It works by blocking the hormone (serotonin) that causes vomiting.

Ondansetron is in a class of medications called 5-HT3 receptor antagonists. It works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.
Ondansetron comes as a tablet, a rapidly disintegrating (dissolving) tablet, and an oral solution to take by mouth. The first dose of ondansetron is usually taken 30 minutes before the start of chemotherapy, 1 to 2 hours before the start of radiation therapy, or 1 hour before surgery. Additional doses are sometimes taken one to three times a day during chemotherapy or radiation therapy and for 1 to 2 days after the end of treatment. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ondansetron exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking the rapidly disintegrating tablet, remove the tablet from the package just before you take your dose. To open the package, do not try to push the tablet through the foil backing of the blister Instead, use dry hands to peel back the foil backing. Gently remove the tablet and immediately place the tablet on the top of your tongue. The tablet will dissolve in a few seconds and can be swallowed with saliva.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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91 022 30601000.
This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009