Taj Pharmaceuticals Ltd.

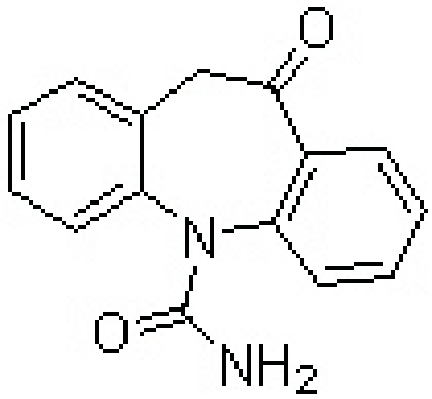
Oxcarbazepine

CAS No. : 28721-07-5

Systematic (IUPAC) name

10,11-Dihydro-10-oxo-5 H -dibenz(b,f)azepine-5-carboxamide

CAS number 28721-07-5
Formula C15H12N2O2
Molecular Weight 252.27



Identifiers

ATC code N03AF02
PubChem 34312
DrugBank APRD01308
ChemSpider 31608

Chemical data

Mol. mass 252.268 g/mol
SMILES eMolecules & PubChem
Pharmacokinetic data
Bioavailability > 95%.

Protein binding ?
Metabolism Hepatic
(Cytosolic Enzymes & Glucuronic Acid)
Half life 1-5 hours (healthy adults)
Excretion Renal

DOSAGE

Take this medication by mouth, usually twice daily. This drug may be taken with or without food. The dosage is based on your medical condition and response to therapy. It is important to take all doses on time to keep the level of medication in your blood constant. Take doses at evenly spaced intervals. Do not skip doses. Do not suddenly stop taking this drug without your doctor's approval since seizures may reoccur. Notify your doctor if seizure control worsens.Oxcarbazepine comes as a tablet and a suspension (liquid) to take by mouth. It is usually taken every 12 hours (twice a day) with or without food. Take oxcarbazepine at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take oxcarbazepine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Shake the suspension well right before each use to mix the medication evenly. Use the oral dosing syringe that came with the medication to withdraw the right amount of suspension from the bottle. You can swallow the suspension straight from the syringe, or you can mix it with a small glass of water and swallow the mixture. Wash the syringe with warm water and allow it to dry thoroughly after use.Your doctor will probably start you on a low dose of oxcarbazepine and gradually increase your dose, not more often than once every three days. If you were taking another medication to treat your seizures and are switching to oxcarbazepine, your doctor may gradually decrease your dose of the other medication while increasing your dose of oxcarbazepine. Follow these directions carefully and ask your doctor if you are not sure how much medication you should take.

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Oxcarbazepine may help control your seizures but will not cure your condition. Continue to take oxcarbazepine even if you feel well. Do not stop taking oxcarbazepine without talking to your doctor. If you suddenly stop taking oxcarbazepine, your seizures may get worse. Your doctor will probably decrease your dose gradually.

SIDE EFFECTS

Dizziness, drowsiness, fatigue, nausea, vomiting, headache, trouble sleeping, acne, dry mouth, or constipation may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. This medication rarely may cause mood or behavior changes, such as anxiety, agitation, hostility, pressured/rapid speech, or thoughts of suicide. Tell your doctor immediately if you develop unusual (possibly sudden) mood changes.

PRECAUTIONS

Before taking oxcarbazepine, tell your doctor or pharmacist if you are allergic to it; or to carbamazepine; or if you have any other allergies. Tell your doctor your medical history, including: kidney disease, decreased sodium blood levels (hyponatremia), recent seizures. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. Oxcarbazepine is not recommended for use during pregnancy due to potential fetal harm. Consult your doctor for more details. This medication passes into breast milk and may have undesirable effects on a nursing infant. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

INTERACTION

Oxcarbazepine was evaluated in human liver microsomes to determine its capacity to inhibit the major cytochrome P450 enzymes responsible for the metabolism of other drugs. Results demonstrate that oxcarbazepine and its pharmacologically active 10-monohydroxy metabolite (MHD) have little or no capacity to function as inhibitors for most of the human cytochrome P450 enzymes evaluated (CYP1A2, CYP2A6, CYP2C9, CYP2D6, CYP2E1, CYP4A9 and CYP4A11) with the exception of CYP2C19 and CYP3A4/5. Although inhibition of CYP3A4/5 by oxcarbazepine and MHD did occur at high concentrations, it is not likely to be of clinical significance. The inhibition of CYP2C19 by oxcarbazepine and MHD, however, is clinically relevantIn vitro, the UDP-glucuronyl transferase level was increased, indicating induction of this enzyme. Increases of 22% with MHD and 47% with oxcarbazepine were observed. As MHD, the predominant plasma substrate, is only a weak inducer of UDP-glucuronyl transferase, it is unlikely to have an effect on drugs that are mainly eliminated by conjugation through UDP-glucuronyl transferasen addition, oxcarbazepine and MHD induce a subgroup of the cytochrome P450 3A family (CYP3A4 and CYP3A5) responsible for the metabolism of dihydropyridine calcium antagonists, oral contraceptives and cyclosporine resulting in a lower plasma concentration of these drugs.As binding of MHD to plasma proteins is low (40%), clinically significant interactions with other drugs through competition for protein binding sites are unlikely.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription medication you may use, especially: calcium channel blockers , other seizure control medication (e.g., carbamazepine, phenytoin, phenobarbital, valproic acid). This medication may decrease the effectiveness of combination-type birth control pills. You may need to use an additional form of reliable birth control while using this medication. Consult your doctor or pharmacist. Tell your doctor if you take any drugs that make you drowsy, such as: medicine for sleep, sedatives, tranquilizers, anti-anxiety drugs (e.g., diazepam), narcotic pain relievers (e.g., hydrocodone, codeine), psychiatric medicines (e.g., phenothiazines such as chlorpromazine, or tricyclics such as amitriptyline), muscle relaxants, antihistamines that cause drowsiness (e.g., diphenhydramine). Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about the safe use of those products. Do not start or stop any medicine without doctor or pharmacist approval.

DRUG DESCRIPTION

Oxcarbazepineis an anticonvulsant and mood stabilizing drug, used primarily in the treatment of epilepsy and bipolar disorder.Oxcarbazepine is a structural derivative of carbamazepine, adding an extra oxygen atom on the dibenzazepine ring. This difference helps reduce the impact on the liver of metabolizing the drug, and also prevents the serious forms of anemia or agranulocytosis occasionally associated with carbamazepine. Aside from this reduction in side effects, it is thought to have the same mechanism as carbamazepine - sodium channel inhibition (presumably, the main mechanism of action) - and is generally used to treat the same conditions. Oxcarbazepine has recently been found associated with a greater enhancement in mood and reduction in anxiety symptoms than other drugs employed to treat epilepsy.

Oxcarbazepine is a white to faintly orange crystalline powder. It is slightly soluble in chloroform, dichloromethane, acetone, and methanol and practically insoluble in ethanol, ether and water. Its molecular weight is 252.27. contains the following inactive ingredients: ascorbic acid; dispersible cellulose; ethanol; macrogol stearate; methyl parahydroxybenzoate; propylene glycol; propyl parahydroxybenzoate; purified water; sodium saccharin; sorbic acid; sorbitol; yellow-plum-lemon aroma.

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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