Taj Pharmaceuticals Ltd.

Cefditoren Pivoxil

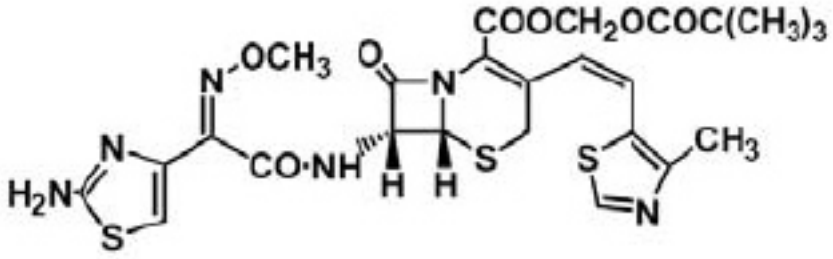
CAS No. : 33817-20-8

Systematic (IUPAC) name

2,2-dimethylpropanoyloxymethyl (2S,5R,6R)-6-{[(2R)-2-amino-2-phenyl-acetyl]amino}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate

Identifiers

CAS number 33817-20-8
ATC code J01CA02
PubChem 33478



cefditoren pivoxil

Chemical data

Formula C22H29N3O6S
Mol. mass 463.548 g/mol

cefditoren pivox il, a semi-synthetic cephalosporin antibiotic for oral administration. It is a prodrug which is hydrolyzed by esterases during absorption, and the drug is distributed in the circulating blood as active cefditoren.

Chemically, cefditoren pivoxil is (-)-(6R,7R)-2,2-dimethylpropionyloxymethyl 7-[(Z)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetamido]-3-[(Z)-2-(4-methylthiazol-5-yl)ethenyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate.
The empirical formula is C25H28N6O7S3 and the molecular weight is 620.73.

The amorphous form of cefditoren pivoxil developed for clinical use is a light yellow powder. It is freely soluble in dilute hydrochloric acid and soluble at levels equal to 6.06 mg/mL in ethanol and < 0.1 mg/mL in water.

SIDE EFFECTS

Diarrhea, headache, nausea/vomiting, or stomach upset may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: shortness of breath, swelling of the ankles/feet, muscle weakness, increased hunger, increased thirst/urination, dark urine, persistent nausea/vomiting, yellowing eyes/skin, change in the amount of urine.
Tell your doctor immediately if any of these rare but very serious side effects occur: new signs of infection (e.g., fever, persistent sore throat), easy bleeding/bruising, tiredness, fast/pounding heartbeat, seizures.

This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool.

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PRECAUTIONS

Before taking cefditoren, tell your doctor or pharmacist if you are allergic to it; or to penicillins or other cephalosporin antibiotics (e.g., cephalexin); or to milk protein (not lactose intolerant); or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: certain metabolic disorders (e.g., carnitine deficiency).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, decreased muscle mass, stomach/intestinal disease (e.g., colitis).

Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side effects while using this drug.

INTERACTION

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: drugs that decrease stomach acid (e.g., antacids, H2 blockers such as ranitidine), live bacterial vaccines, probenecid, warfarin.

This medication may interfere with certain laboratory tests (including Coombs' test, certain urine glucose tests), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

This document does not contain all possible interactions.

Therefore, before using this product, tell your doctor or pharmacist of all the products you use.

Keep a list of all your medications with you, and share the list with your doctor

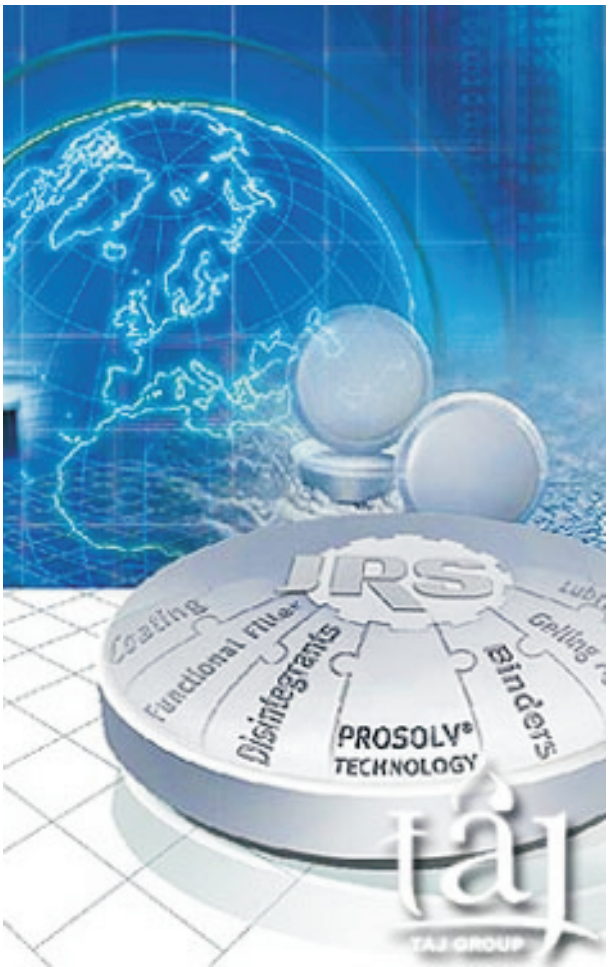
DOSAGE

Patients with Renal Insufficiency

No dose adjustment is necessary for patients with mild renal impairment . It is recommended that not more than 200 mg BID be administered to patients with moderate renal impairment and 200 mg QD be administered to patients with severe renal impairment . The appropriate dose in patients with end-stage renal disease has not been determined.

Patients with Hepatic Disease

No dose adjustments are necessary for patients with mild or moderate hepatic impairment . The pharmacokinetics of cefditoren have not been studied in patients with severe hepatic impairment



Take this medication by mouth with meals, usually twice daily or as directed by your doctor.

The dosage is based on your medical condition and response to therapy.

Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals.

Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture 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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