Irbesartan Cas No. : 138402-11-6

This drug is used to treat high blood pressure (hypertension) and to help protect the kidneys from damage due to diabetes. High blood pressure reduction helps prevent strokes, heart attacks, and kidney problems. This drug works by blocking the hormone angiotensin thereby relaxing blood vessels, causing them to widen.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd. Irbesartan CAS No. : 138402-11-6

Systematic (IUPAC) name

2-butyl-3-({4-[2-(2H-1,2,3,4-tetrazol-5-yl)phenyl]phenyl}methyl)-1,3-diazaspiro[4.4]non-1-en-4-one

Identifiers

CAS number 138402-11-6 ATC code C09CA04 PubChem 3749 DrugBank APRD00413

Chemical data

Molecular Weight 428.54 Formula C25H28N6O Mol. mass 428.53 SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability 60–80% Metabolism Hepatic (CYP2C9) Half life 11–15 hours Excretion Renal 20%, faecal 65%

USES

This drug is used to treat high blood pressure (hypertension) and to help protect the kidneys from damage due to diabetes. High blood pressure reduction helps prevent strokes, heart attacks, and kidney problems. This drug works by blocking the hormone angiotensin thereby relaxing blood vessels, causing them to widen. Irbesartan belongs to a class of drugs called angiotensin receptor blockers.

OTHER USES

This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

HOW TO USE

Take this medication by mouth, usually once daily or as directed by your doctor. You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time each day.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.



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Taj Pharmaceuticals Ltd.

Irbesartan

CAS NO- 138402-11-6

STORAGE

Store at room temperature between 59 and 86 degrees F (15 to 30 "degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

Take this medication by mouth, usually once daily or as directed by your doctor. You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time each day. Do not take potassium supplements or salt substitutes containing potassium without talking to your doctor or pharmacist first. This medicine can raise your potassium levels, which rarely can



cause serious side effects such as muscle weakness or very slow heartbeats. Tell your doctor immediately if these effects occur. The dosage is based on your medical condition and response to therapy. For the treatment of high blood pressure, it may take 2 weeks before the full benefit of this drug occurs. It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick.

Take your dose of Avapro around the same time every day, with or without food..

SIDE EFFECTS

You may experience dizziness, lightheadedness, blurred vision, stomach upset, or heartburn as your body adjusts to the medication. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: fainting, decreased sexual ability. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: change in the amount of urine, stomach/abdominal pain, severe nausea, yellowing eyes or skin, dark urine, unusual fatigue. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling (especially of the face, lips, tongue, or throat), severe dizziness, trouble breathing

In people taking Avapro for diabetic kidney disease, the most common side effects are dizziness, dizziness when standing up, or low blood pressure when standing up.

PRECAUTIONS

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, high blood levels of potassium, heart problems, severe dehydration (and loss of electrolytes such as sodium), diabetes (poorly controlled), any allergies (especially to ACE inhibitors such as captopril, lisinopril). This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. Before having surgery, tell your doctor or dentist that you are taking this medication. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug, especially the dizziness effect. This medication should be used only when clearly needed during the first three months of pregnancy. It is not recommended for use during the last six months of the pregnancy due to the risk for fetal harm. Discuss the risks and benefits with your doctor. See also the Warning section. It is not known if this drug passes into breast milk. Breast-feeding is not recommended due to the potential harm to the nursing infant. Consult your doctor before breast-feeding.



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PHARMACEUTICALS ACTIVE PHARMACEUTICAL INGREDIENTS

DRUG DESCRIPTION

Irbesartan is a white to off-white crystalline powder with a molecular weight of 428.5. It is a nonpolar compound with a partition coefficient (octanol/water) of 10.1 at pH of 7.4. Irbesartan is slightly soluble in alcohol and methylene chloride and practically insoluble in water.

Irbesartan is among a class of drugs called angiotensin receptor blockers and is similar to losartan (Cozaar) and valsartan (Diovan). All three drugs block angiotensin II, a chemical that causes the arteries and veins to narrow, from attaching to the arteries and veins and causing them to narrow. As a result, the arteries and veins dilate (become larger), and blood pressure is reduced. When the blood pressure is reduced, the heart doesn't have to work as hard to pump blood.

This drug is used in adults and in children 6 years of age and older to treat high blood pressure (hypertension) and to help protect the kidneys from damage due to diabetes. This drug works by blocking the hormone angiotensin thereby relaxing blood vessels, causing them to widen. High blood pressure reduction helps prevent strokes, heart attacks, and kidney problems.

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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

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at: http://www.tajapi.com or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000. This leaflet was prepared by

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