



DRUG CLASS AND MECHANISM

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. Irbesartan was approved by the FDA in 1998.

PRESCRIPTION: yes

PREPARATIONS: Tablets: 75mg, 150mg, 300mg.

PRESCRIBED FOR: Irbesartan is used to treat high blood pressure. It may be used alone or in combination with other drugs. It has less of an effect in black patients, an effect that is similar to another class of drugs used to treat high blood pressure called ACE inhibitors--captopril (Capoten), enalapril (Vasotec), benazepril (Lotensin), and lisinopril (Zestril). Irbesartan is being studied in patients with congestive heart failure to determine if its blood pressure-lowering effects are beneficial to the heart.

DOSING

Irbesartan usually is taken once daily.

DRUG INTERACTIONS

See also How to Use section. Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: lithium, "water pills" (potassium-sparing diuretics such as amiloride, spironolactone, triamterene). Check the labels on all your medicines (e.g., cough-and-cold products, diet aids, nonsteroidal anti-inflammatory drugs - NSAIDs such as ibuprofen and naproxen for pain/fever reduction) because they may contain ingredients that could increase your blood pressure. Ask your pharmacist about the safe use of those products. Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually at dosages of 81-325 milligrams per day), should be continued. Consult your doctor or pharmacist for more details. 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 and pharmacist.

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 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. This drug may also be used to treat congestive heart failure.

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.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.

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.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: 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, muscle

pain/tenderness/weakness. 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/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US -Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking **irbesartan**, tell your doctor or pharmacist if you are allergic to it; or to ACE inhibitors (e.g., benazepril, captopril); or if you have any other allergies.Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, high blood levels of potassium, severe dehydration (and loss of electrolytes such as sodium).This drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. 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 is not recommended for use during pregnancy due to the risk for harm to an unborn baby. Consult your doctor for more details. (See also 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.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include unusually fast or slow heartbeat, severe dizziness or fainting.

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.

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.Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA), or 1-800-668-1507 (Canada).

WARNING: This drug can cause serious (possibly fatal) harm to an unborn baby if used during pregnancy. Therefore, it is important to prevent pregnancy while taking this medication. Consult your doctor for more details and to discuss the use of reliable forms of birth control while taking this medication. If you are planning pregnancy, become pregnant, or think you may be pregnant, contact your doctor immediately.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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