

Adizar 50 mg; 100 mg film-coated tablets

Losartan potassium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Adizar is and what it is used for
2. What you need to know before you take Adizar
3. How to take Adizar
4. Possible side effects
5. How to store Adizar
6. Contents of the pack and other information

1. What Adizar is and what it is used for

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists.

Angiotensin II is a substance produced in the body which binds to receptors in blood vessels causing them to contract. As a result, blood pressure increases. Losartan prevents the binding of angiotensin II to these receptors by causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Adizar is used :

- to treat patients with high blood pressure (hypertension) including in adults, children and adolescents aged 6-18 years.
- to protect the kidney in hypertensive patients with type 2 diabetes, with laboratory findings of impaired renal function and proteinuria ≥ 0.5 g/day (a condition in which urine contains abnormally high amount of protein).
- to treat patients with chronic heart failure when the treatment with some drugs known as angiotensin converting enzyme inhibitors (ACE inhibitors – medications used for blood pressure lowering) are not considered appropriate by your doctor. If your heart failure has been stabilized by an ACE inhibitor, you should not switch to losartan
- in patients with high blood pressure and a thickening of the left ventricle, Adizar has been shown to reduce the risk of stroke (“LIFE” indication).

2. What you need to know before you take Adizar

Do not take Adizar:

- if you are allergic to losartan or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is better to avoid Adizar also in early pregnancy -see “Pregnancy and breast –feeding”)
- if you have a severely impaired liver function
- if you have diabetes or impaired kidney function and you are treated with a blood lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Adizar.

You must tell your doctor if you think you are (or might be) pregnant. Adizar is not recommended for use in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby (see “Pregnancy” section).

It is important to tell your doctor before taking Adizar:

- if you have a history of angioedema (swelling in the face, lips, throat, and/or tongue (see also section 4 “Possible side effects”)),
- if you suffer from excessive vomiting or diarrhea leading to an extreme loss of fluid and/or salt in your body,
- if you receive diuretics (medicines that increase the amount of fluid eliminated through your kidneys) or if you are under dietary salt restriction leading to an extreme loss of fluid in your body (see section 3 “Dosage in special patient groups”)
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have recently received a kidney transplant,
- if your liver function is impaired (see section 2 “Do not take Adizar and 3 “Dosage in special patient groups”)
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is required when you are treated with a β - blocker concomitantly,
- if you have problems with your heart valves or heart muscle,
- if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain)
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal glands, caused by an abnormality within the glands)
- if you are taking any of the following medicines used to treat high

blood pressure:

- an ACE inhibitor (e.g. enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
- aliskiren

Your doctor may periodically check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood.

See also the information under “Do not take Adizar”.

Children and adolescents

Adizar has been studied in children. For more information, talk to your doctor.

Adizar is not recommended for use in children suffering from kidney or liver problems, as limited data exist in these patient groups.

Adizar not recommended for use in children under the age of 6 years as it has not been shown to have an effect in this age group.

Other medicines and Adizar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Take special care if you are taking the following medicines while under treatment with Adizar:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine;
- drugs that retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics (amilofide, triamterene, spironolactone) or heparin);
- non-steroidal anti-inflammatory drugs such as indomethacin, including cox-2-inhibitors (medicines that inhibit inflammation, and can be used to relieve pain) as they may reduce the blood pressure lowering effect of losartan.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information under “Do not take Adizar” and “Warnings and precautions”).

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan without continuous supervision by your doctor. Special precautionary measures (e.g. blood tests) may also be appropriate.

Adizar with food and drink

Adizar may be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will advise you to stop taking Adizar before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Adizar. Adizar is not recommended for use in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used after the 3rd month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or starting to breast-feed. Adizar is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is a newborn, or born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies have been conducted on the drug effects on the ability to drive and use machines. Adizar is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Adizar contains lactose monohydrate

This medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Adizar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of Adizar depending on your condition and whether you are taking other medicines. It is important to continue the treatment for as long as your doctor prescribes it in order to maintain good control of your blood pressure. **Adult patients with high blood pressure**

Treatment usually starts with 50 mg losartan (one Adizar tablet 50 mg) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg losartan (two Adizar tablets 50 mg or one tablet of Adizar 100 mg) once daily. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

Use in children and adolescents

Children below the age of 6 years

Adizar is not recommended for use in children below 6 years of age as it has not been shown to be effective in this age group.

Children aged 6-18 years

The recommended starting dose in patients with body weight between 20 and 50 kg is 0,7 mg of losartan per kg of body weight administered once a day (up to 25 mg Adizar). The doctor may increase the dose if the blood pressure could not be controlled.

Other forms of this medicinal product may be more suitable for children; ask your doctor or pharmacist.

Adult patients with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg Adizar once a day. The dose may later be increased to 100 mg losartan (two Adizar tablets 50 mg or one tablet of Adizar 100 mg) once daily depending on your blood pressure response.

Adizar tablets may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

Adult patients with heart failure

Treatment usually starts with 12,5 mg losartan (one Adizar tablet 12,5 mg) once a day. Normally the dose should be increased gradually per week (i.e. 12,5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as prescribed by your doctor. A maximum dose of 150 mg losartan (e.g. 3 tablets of Adizar 50 mg or one table Adizar 100 mg and one tablet Adizar 50 mg) may be used once a day.

In treatment of patients with heart failure, losartan is usually combined with diuretics (medicines that increase the amount of fluid eliminated through the kidneys) and/or digitalis (medicine that helps the heart to be healthier and more effective) and/or beta-blocker.

Dosage in special patient groups

The doctor may recommend a lower dose, particularly at the start of treatment of specific patients such as those treated with high dose diuretics, patients with liver impairment or patients aged more than 75 years. Losartan use is not recommended in patients with severe liver impairment (see section "Do not take Adizar").

Method of administration

The tablet should be swallowed with a glass of water. You should try to take your tablets at the same time each day. It is important that you continue to take Adizar until your doctor tells you otherwise.

If you take more Adizar than you should

If you accidentally take too many tablets, contact your doctor immediately.

Symptoms of overdose are low blood pressure, increased heart rate, possibly decreased heart rate.

If you forget to take Adizar

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience the following, stop taking Adizar and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10 000 patients but less than 1 out of 1 000 patients. You may need urgent medical attention or hospitalization.

The following side effects have been reported with Adizar:

Common (may affect up to 1 in 10 patients):

- dizziness
- low blood pressure (especially after excessive loss of fluid from the circulating blood in the body, e.g. in patients with severe heart failure or under treatment with high dose diuretics),
- dose-related orthostatic effects such as lowering of blood pressure appearing when standing up from a lying or sitting position,
- weakness
- fatigue
- too low level of sugar in the blood (hypoglycaemia),
- too high level of potassium in the blood (hyperkalemia),
- changes in kidney function including kidney failure

- reduced number of red blood cells (anaemia),
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Uncommon (may affect up to 1 in 100 patients),

- somnolence
- headache
- sleep disorders
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris)
- shortness of breath (dyspnoea)
- abdominal pain
- constipation
- diarrhea
- nausea
- vomiting
- hives (urticaria)
- itching (pruritus),
- rash
- localised swelling (oedema)
- cough

Rare (may affect up to 1 in 1,000 patients):

- hypersensitivity
- angioedema (swelling of the face, lips, throat and/or tongue),
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation),
- brain insult (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels usually resolved upon discontinuation of treatment.

Not known (frequency cannot be estimated from available data):

- reduced number of thrombocytes,
- migraine,
- liver function abnormalities
- muscle and joint pain,
- flu-like symptoms
- back pain and urinary tract infection,
- increased sensitivity to sunlight (photosensitivity),
- unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis),
- impotence,
- inflammation of the pancreas (pancreatitis),
- low levels of sodium in the blood (hyponatremia),
- depression,
- general feeling of discomfort (malaise),
- ringing, buzzing, roaring, or clicking in the ears
- disturbed taste (dysgeusia).

The side effects in children are similar to those seen in adults.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adizar

Keep this medicine out of the sight and reach of children.

Store in the original package below 30°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Adizar contains

- The active substance is losartan potassium. Each tablet contains 50 mg or 100 mg losartan potassium.
- The other ingredients (excipients) are: microcrystalline cellulose (E460), lactose monohydrate, pregelatinised starch, magnesium stearate (E572), hypromellose (E463), hypromellose (E464)

What Adizar looks like and contents of the pack

Adizar is white round film-coated tablets containing 50 mg or 100 mg losartan potassium.

The tablets are packed in blisters of PVC/aluminum foil, 30 tablets per pack.

Marketing Authorisation Holder and Manufacturer

Adipharm EAD

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