

# Adizar H 50 mg/12,5 mg; 100 mg/12,5 mg film-coated tablets

**Losartan potassium / hydrochlorothiazide**

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

#### 1. What Adizar H is and what it is used for

Adizar H is a combination of angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Angiotensin II is a substance produced in the body which binds to receptors on 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. Hydrochlorothiazide stimulates water and salt elimination through the kidneys. This also helps blood pressure lowering.

Adizar H is indicated for treatment of essential hypertension (high blood pressure).

#### 2. What you need to know before you use Adizar H

##### Do not use Adizar H:

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to a group of medicines known as sulfonamide derivatives (e.g. other thiazides, some medicines for treatment of bacterial infections such as trimoxazole; check with your doctor if you are not sure);
- if you have a severely impaired liver function;
- if you have a low level of potassium, low level of sodium or high levels of calcium that cannot be controlled by treatment;
- if you suffer from gout;
- if you are more than 3 months pregnant (It is better to avoid LOZAP H also in early pregnancy -see "Pregnancy and breast-feeding")
- if you have a severely impaired kidney function, and urine cannot be eliminated through your kidneys
- if you have diabetes or impaired kidney function, and are under treatment with aliskiren-containing blood pressure-lowering medicine.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Adizar H

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. Adizar H 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 also "Pregnancy and Breast-feeding" section).

It is important to tell your doctor before taking Adizar H:

- if you have a history of swelling in the face, lips, throat and/or tongue
- if you receive diuretics (medicines that increase the amount of fluid eliminated through your kidneys)
- if you are under dietary salt restriction
- if you suffer or have suffered from excessive vomiting or diarrhea
- if you suffer from heart failure
- if your liver function is impaired (see section 2 "Do not use Adizar H")
- if you have narrowing of the arteries leading to your kidneys (renal artery stenosis) or if you have only one functioning kidney, or if you have recently received a kidney transplant
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to limited blood oxygen supply to the heart muscle)
- if you have aortic or mitral stenosis (narrowing of the heart's valves) or hypertrophic cardiomyopathy (a disease causing the thickening of the heart muscle)
- if you have diabetes

- if you have a history of gout
- if you have or have had an asthmatic condition, asthma
- if you have or have had systemic lupus erythematosus (a disease manifesting as joint pain, skin rash and fever)
- if you have high levels of calcium and low levels of potassium, or are under dietary potassium restriction
- if you must undergo anesthesia (even dental) before a surgical procedure, or if you need a parathyroid function test, you must tell your doctor or medical staff that you are taking Adizar H
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal 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 check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also the information under "Do not take Adizar H".

#### Children and adolescents

There is no experience with the use Adizar H in children and adolescents (<18 years), therefore Adizar H should not be given to children and adolescents.

#### Other medicines and Adizar H

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

Diuretics such as hydrochlorothiazide contained in Adizar H, may interact with other medicines.

Lithium-containing products should not be concomitantly used with Adizar H without close supervision by your doctor.

Special precautions may be appropriate (e.e. blood tests if you are taking potassium supplements, potassium-containing substitutes or potassium sparing medicines, or other diuretics (medicines that increase the amount of eliminated fluid), some laxatives, medicines for treatment of gout, heart rhythm control medications).

It is also important to inform your doctor that you are taking other blood pressure lowering medicines, steroids, anti-cancer drugs, pain relief drugs or medicines for treatment of arthritis, medicines for treatment of fungal infections, resins used in case of high cholesterol levels such as cholestiramine, muscle relaxants, antidepressants, sleeping pills, opiates such as morphine, pressor amines such as adrenaline or other drugs from the same group; oral antidiabetics or insulins, carbamazepine used in epilepsy treatment.

Your doctor may need to adjust your dose and/or take other precautionary measures:

- If you are taking an ACE inhibitor or aliskiren (see also the information under "Do not use Adizar H" and "Warnings and precautions")

You must inform your doctor that you are under treatment with Adizar H if you are to have an X-Ray procedure or an administration of iodine contrast media.

#### Adizar H with food, drink and alcohol

It is advisable not to drink alcohol while you are taking these tablets: alcohol and Adizar H tablets may mutually potentiate one another's effects.

Excessive use of salt with food may counteract the effect of Adizar H tablets. Adizar H may be used with or without food.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

You must inform your doctor if you are pregnant or are planning to have a baby. Your doctor will advise you to stop taking Adizar H before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Adizar H. Adizar H 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 3<sup>rd</sup> month of pregnancy.

#### Breast-feeding

You should inform your doctor if you are breast-feeding or are

planning to breast-feed. Adizar H is not recommended for breast-feeding mothers, therefore your doctor may choose another treatment if you wish to breast-feed.

### Driving and using machines

When you start treatment with this medicine, you should not perform tasks that require special attention (for example, driving a car or operating machinery) until you know how you tolerate the medicine.

### Adizar H contains Lactose monohydrate

If your doctor has told you that you have intolerance to some sugars, you should consult him before taking this medicine.

### 3. How to use Adizar H

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the appropriate dose of Adizar H 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.

Adizar H may be used with or without food.

#### High blood pressure

The recommended dose of Adizar H for most patients with high blood pressure is one tablet Adizar H 50 mg/12,5 mg once a day for blood pressure control for a 24-hour period. It may be increased to 2 tablets Adizar H 50 mg/12,5 mg once daily or 1 tablet Adizar H 100 mg/25 mg.

The maximum daily dose is 2 tablets Adizar H 50 mg/12,5 mg or 1 tablet Adizar H 100 mg/25 mg.

Adizar H 100 mg/12,5 mg is available for patients who need additional blood pressure control after being titrated to 100 mg of losartan.

#### Use in children

There is no experience with the use of Adizar H in children. Therefore, Adizar H should not be used in children.

#### Use in elderly patients

The effect of Adizar H is similar in young patients and in elderly patients. Most elderly patients require the same dose as the younger patients.

#### If you use more Adizar H than you should

If you accidentally take too many tablets, contact your doctor immediately or go to a hospital to receive the required medical care. Symptoms of overdose are low blood pressure, increased heart rate, possibly decreased heart rate, changes in blood composition, and dehydration.

#### If you forget to use Adizar H

Try to take Adizar H according to prescription. If however, you miss a dose, do not take a double dose. Just take the next dose as normal.

#### If you stop taking Adizar H

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. 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 H 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 losartan and hydrochlorothiazide (active substances of Adizar H):

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

- cough, upper respiratory tract infections, nasal congestion, sinusitis, sinus disorders
- diarrhea, abdominal pain, nausea, dyspepsia
- muscle pain or spasm, pain in the leg, pain in the spine
- insomnia, headache, dizziness
- weakness, fatigue, chest pain
- too high level of potassium in the blood (which may cause rhythm disorders), low levels of hemoglobin
- changes in the kidney function including kidney failure
- too low level of sugar in the blood (hypoglycaemia).

#### Uncommon (may affect up less than 1 in 100 patients):

- anemia, red or brownish spots in the skin (sometimes on soles, feet, hands and hips, and stomach pain), decrease in white blood cell count, blood coagulation problems, bruising

- loss of appetite, elevated uric acid levels or gout, increased blood glucose levels, abnormal blood levels of electrolytes
- anxiety, nervousness, panic disorders (repeated panic attacks), confusion, depression, abnormal dreams, sleep disturbance, somnolence, impaired memory
- Numbness or similar feeling, limb pain, tremor, migraine, loss of consciousness
- Blurred vision, burning or stinging in the eye, conjunctivitis, decrease in visual acuity, yellow vision
- Ringing, buzzing, roaring or clicking in the ears, vertigo
- Low blood pressure that may be postural (dizziness or weakness at standing up, angina (chest pain), abnormal heart rate, cerebrovascular event (transient ischaemic attack, "mini-stroke"), heart attack, palpitations
- Blood vessel inflammation which is often associated with skin rash or bruising
- Sore throat, shortness of breath, bronchitis, pneumonia, water accumulation in the lungs (causing difficulty in breathing), nose bleed, nasal discharge, nasal blockage
- Constipation, flatulence, nervous stomach, stomach spasms, vomiting, dry mouth, salivary gland inflammation, toothache
- Jaundice (yellowing of the eyes and skin), pancreatic inflammation
- Hives, itching, skin inflammation, rash, skin redness, sensitivity to light, dry skin, blushing, sweating, hair loss
- Pain in the hands, shoulders, legs, knees or other joints, swelling of the joints, numbness, muscle weakness
- Frequent urination, particularly at night, abnormal kidney function including inflammation of the kidneys, urinary tract infections, sugar in the urine
- Low sodium level in the blood (hyponatremia)
- Decreased sexual desire, impotence
- Swelling in the face, localised swelling (oedema), fever

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

- Hepatitis (inflammation of the liver), abnormal liver function tests

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

- unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis),
- flu-like symptoms
- general feeling of discomfort (malaise),
- allergic condition causing joint pain, skin rash and fever
- disturbed taste (dysgeusia).

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 H

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

Store at temperature below 30°C.

Do not use this medicine after the expiry date which is stated on the pack after Exp. 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 H contains

The active substances is: losartan 50 mg or 100 mg and hydrochlorothiazide 12,5 mg in one tablet.

The other ingredients (excipients) are: lactose monohydrate, pregelatinised maize starch, microcrystalline cellulose, magnesium stearate, hydroxypropylcellulose, hydroxypropylmethylcellulose, titanium dioxide

#### What Adizar H looks like and contents of the pack

Adizar H is yellow film-coated tablets containing 50 mg or 100 mg losartan potassium and 12,5mg hydrochlorothiazide.

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

#### Marketing Authorisation Holder and Manufacturer

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