



Adipril H 5 mg/12,5 mg tablets

Adipril H 10 mg/12,5 mg tablets

Adipril H 20 mg/12,5 mg tablets

Lisinopril/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, please 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.

What is in this leaflet:

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

1. What Adipril H is and what it is used for

Adipril H is a combination product containing 2 medications: lisinopril and hydrochlorothiazide. It is used to **treat high blood pressure**.

Lisinopril belongs to a class of medications called *ACE inhibitors* and helps to lower blood pressure by relaxing blood vessels and reducing the workload of the heart. Hydrochlorothiazide belongs to a class of medications called *diuretics* or „water pills“ that help control blood pressure by getting rid of excess salt and water.

Both components have independent action and in combination exhibit mutual upward effect on lowering blood pressure.

Adipril H is used to treat hypertension (high blood pressure) when there is not adequate control of blood pressure when treated with lisinopril and/or in patients whose blood pressure is stabilized with the individual components at the same doses.

2. What you need to know before you take Adipril H

Do not take Adipril H:

- if you are allergic (hypersensitive) to the active substance, to other quinolone drugs or to any of the other ingredients of Adipril H (see section 6) as well as other medicines of group of ACE inhibitors and sulphonamides;
- if you have a history of angioedema after taking any ACE inhibitors (e.g., captopril, enalapril, fosinopril, lisinopril, ramipril);
- are pregnant or intend to become pregnant;
- severe kidney or hepatic impairment;
- have difficulty producing urine or are unable to urinate.

Warnings and precautions

Talk to your doctor or pharmacist before taking Adipril H.

Tell your doctor if:

- you have ever had an allergic reaction with swelling of face, lips, tongue and / or throat with difficulty in swallowing and breathing;
- you are on a diet low in salt;
- conducting long-term therapy with diuretics;
- you have kidney disease (or if you are on dialysis);
- you have diarrhoea or vomiting continuously;
- have narrowing of the renal artery;
- suffer from heart disease (heart disease that can lead to fatigue, shortness of breath, swollen ankles, etc.);
- have angina (attack of chest pain);
- have cerebrovascular disorders;
- have kidney problems or you have had a kidney transplantation;
- have impaired liver function or liver disease;
- you are having desensitisation treatment for bee and wasp stings;

- you await a surgical operation;
- have diabetes;
- if you suffer from a collagen vascular disease, such as systemic lupus erythematosus (SLE) or scleroderma;
- being treated with medicines that suppress the immune system;
- you have bronchial asthma;
- suffer from gout;

Tell your doctor immediately, if any of the following occurs **while taking Adipril H**.

In the event of facial swelling, lips, tongue, throat and / or larynx and, extremities immediately discontinue therapy and contact emergency medical care!

Tell your doctor and discontinue treatment if you have pain in the abdomen, which may be accompanied by nausea, vomiting and yellowing of the skin. A non-productive, persistent cough has been reported with the use of ACE-inhibitors. The cough resolves after discontinuation of therapy.

The presence of hydrochlorothiazide in this combination may cause a positive shift results in an anti-doping test.

Tell your doctor if you notice symptoms such as nausea or dizziness especially when standing, which indicate low blood pressure.

Please inform your doctor if you think you are pregnant or planning a pregnancy.

Do not use the Adipril H in early pregnancy, it should not be taken for more than 3 months pregnant women, as it may cause serious harm to your baby if used after the third month.

Other medicines and Adipril H

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

Your doctor should know if you are being, or are being treated with diuretics (water pills).

Tell your doctor if you are taking: lithium, potassium supplements, potassium-sparing diuretics or potassium salt, insulin or diabetes medicine taken by mouth, nonsteroidal anti-inflammatory drugs (used to treat joint pain and inflammation, such as diclofenac, indomethacin, ketoprofen, ibuprofen, etc.), allopurinol, cyclosporine, lovastatin, trimethoprim, cardiac glycosides (eg digoxin), sotalol, cholestyramine, colestipol, tubocurarine, tricyclic antidepressants, antiarrhythmic medicines, antipsychotics, corticosteroids, carbonoxolone, corticotropin, laxatives and other products to lower blood pressure, sympathomimetics, procainamide, cytostatics, drugs suppressing immune system, gold containing medicines, calcium salts.

Adipril H with food, drink and alcohol

No evidence of a need for a special diet or restrictions of certain foods and drinks during treatment with this product.

Pregnancy, Breast-feeding and fertility

If you are pregnant or nursing, you think you may be pregnant or plan to become pregnant, talk to your doctor or pharmacist before taking this medicine.

Pregnancy

It is preferable to avoid the use of Adipril H during pregnancy. Tell your doctor if you are planning to get pregnant.

Please inform your doctor if you think you are (or might become) pregnant. Usually the doctor will advise you to stop taking Adipril H before getting pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Adipril H.

Adipril H not recommended in the early months of the pregnancy and should not be taken after the third month of pregnancy, as it can cause serious harm to your baby if used at that stage.

Breast-feeding

Adipril H is not recommended for breast-feeding, and your doctor may

choose another treatment for you if you want to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Like the other blood pressure lowering medicines, the ability to drive and use machines may be mild to moderately affected.

This is more likely at the beginning of treatment, at a dosage adjustment or during concomitant use of alcohol, depending on the individual sensitivity.

Adipril H contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Adipril H.

Adipril H contains lactose. In patients hypersensitive to lactose, the medicine may cause gastrointestinal disturbances.

3. How to take Adipril H

Always take Adipril H exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Adipril H can be taken one or two tablets daily at the same time of day.

Adults

The usual daily dosage is:

Of Lisinopril: 5-80 mg daily.

Of Hydrochlorothiazide: 12.5-50 mg daily.

The maximum daily dose of 80 mg Lisinopril and 50 mg Hydrochlorothiazide should not be exceeded.

Patients with renal insufficiency:

Adipril H is contraindicated in patients with severely impaired renal function. Adipril H may be used in patients with moderate renal impairment, but only after adjustment of the individual components

Use in the Elderly

Dosage in elderly patients is the same as for adults. It is not necessary to reduce the dose in these patients if they are with normal renal and hepatic function.

Use in children and adolescents

This product is not recommended for use in children.

If you take more Adipril H than you should

If you take more than the prescribed dose, get medical help immediately.

Symptoms of overdose include nausea, vomiting, weakness, dizziness, anxiety, palpitations, shortness of breath, cough, disturbances of water and electrolyte balance, very low blood pressure, shock.

If you forget to take Adipril H

Take the normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Adipril H can cause side effects, although not everybody gets them.

The most commonly reported side effects are cough, dizziness, low blood pressure and headaches that can occur in 1 to 10% of patients.

Adverse reactions associated with the implementation of lisinopril:

Common (affect between 1 in 10 and 1 in 100 people):

dizziness, headache, syncope (fainting), low blood pressure when standing, coughing, diarrhoea, vomiting, impaired renal function;

Uncommon (affect between 1 in 100 and 1 in 1000 people):

moodiness, depression, numbness and tingling, dizziness, dysgeusia, sleep disorders, myocardial infarction or cerebrovascular accident, feeling palpitations, rapid heartbeat, Raynaud's syndrome (poor blood supply to the fingers and toes in result, they become stiff and pale); fever, nausea, pain in the abdomen, digestive disorders, elevation of liver enzymes and bilirubin; rash, itching, impotence, fatigue, weakness, elevation of blood urea, serum creatinine and potassium.

Rare (affect between 1 in 1 000 and 1 in 10 000 people):

changes in blood count (decreased hemoglobin and hematocrit); confusion, dry mouth, hypersensitivity / angioneurotic edema: swelling of the face, extremities, lips, tongue, throat and / or vocal cords, urticaria, alopecia, psoriasis, increased nitrogen products in the body, acute renal failure, increased mammary glands in men, lower sodium.

Very rare (affect less than 1 in 10 000 people):

suppression of bone marrow function, anemia (reduction in red blood cells that can cause paleness, weakness, or shortness of breath); low platelets, which increases the risk of bleeding or bruising; reducing to greatly reduce the number of white blood cells, which increases the likelihood of infection; hemolytic anemia (reduce the number of red blood cells, which can lead to pallor or yellowing of the skin, weakness, or shortness of breath), swollen lymph glands, autoimmune diseases, decreases blood sugar; narrowing of the airways with shortness of breath, inflammation of the sinuses, allergic pneumonia; inflammation of the pancreas, swelling of the intestinal wall, liver inflammation (hepatitis, hepatocellular or cholestatic) jaundice, liver failure; sweating, pemphigus, severe illness with blistering of the skin and mucous membranes, such as toxic epidermal necrolysis and Stevens-Johnson syndrome, erythema multiforme, skin pseudolymphoma, reduced or absent urine excretion:

There was an appearance of a syndrome which may include the following symptoms: fever, vascular inflammation, muscle and joint pain, positive ANA (antinuclear antibodies), elevated erythrocyte sedimentation rate, changes in the blood (eosinophilia, leukocytosis), rash, photosensitivity, other skin events.

Adverse reactions associated with the implementation of hydrochlorothiazide

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

inflammation of the salivary glands, reducing to greatly reduce the number of white blood cells, which increases probability of infection, low platelets, which increases risk of bleeding or bruising, aplastic anemia (severe reduction in the number of blood cells, causing weakness, bruising or increased likelihood of infection), hemolytic anemia, suppression of bone marrow function;

anorexia (lack of appetite), high blood sugar, the sugar excretion in the urine, increased uric acid, decreased potassium and sodium in the blood, increased cholesterol and triglycerides, gout, anxiety, depression, sleep disorders; loss of appetite, numbness, dizziness, seeing everything in yellow, transient blurred vision, dizziness, low blood pressure, inflammation and damage to the vessels, lung inflammation and pulmonary edema, gastrointestinal irritation, diarrhea, constipation, pancreatitis; jaundice (intrahepatic cholestatic jaundice), photosensitivity reactions, rash, activation of cutaneous lupus erythematosus, urticaria, allergic reactions (anaphylaxis) epidermal toxic necrolysis, muscle cramps, muscle weakness, impaired renal function, kidney inflammation, fever, weakness

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. How to store Adipril H

Keep out of the reach and sight of children

Do not store above 30 °C.

Do not take this medicinal product after the expiry date noted on the package.

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. Content of the pack and other information

What Adipril H tablets contains

The active substances are: lisinopril and hydrochlorothiazide

Each tablet contains: 5 mg lisinopril (as dihydrate) and 12.5 mg hydrochlorothiazide; 10 mg lisinopril (as dihydrate) and 12.5 mg hydrochlorothiazide; 20 mg lisinopril (as dihydrate) and 12.5 mg hydrochlorothiazide

The other ingredients are:

lactose monohydrate, povidone, crospovidone, cellulose, silica colloidal anhydrous, magnesium stearate.

What Adipril H tablets looks like and contents of the pack

The tablets are packed in blister of PVC/Al foil, 30 tablets per pack.

Marketing authorization holder and manufacturer:

ADIPHARM EAD

130, Simeonovsko shosse Blvd.

Sofia 1700, Bulgaria

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