



# ADIPRIL 5 mg tablets

# ADIPRIL 10 mg tablets

# ADIPRIL 20 mg tablets

## Lisinopril dihydrate

### Read all of this leaflet carefully before you start taking this medicine.

- 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 any of the adverse drug reactions becomes serious or you notice other adverse reactions not listed in this leaflet, please talk to your doctor or pharmacist.

### What is in this leaflet:

1. What Adipril is and what it is used for
2. Before you take Adipril
3. How to take Adipril
4. Possible side effects
5. How to store Adipril
6. Further information

## 1. WHAT ADIPRIL IS AND WHAT IT IS USED FOR

Adipril belongs to a group of medicines, called ACE inhibitors (angiotensin-converting enzyme inhibitors). The therapeutic action of Adipril is manifested by dilation of the blood vessels that helps for reduction of the increased blood pressure and facilitates the heart's pumping the blood to all parts of the body.

Your doctor has prescribed Adipril to you for one of the following reasons:

- if your blood pressure is increased (hypertension);
- if you have impaired heart function, known as heart failure, when the heart cannot pump adequately blood to all parts of the body;
- if you have suffered an acute myocardial infarction that may lead to heart function weakening, Adipril helps the work of the heart and corrects this condition;
- if you have renal complications due to diabetes or increased blood pressure.

## 2. BEFORE YOU TAKE ADIPRIL

Do not take Adipril:

- if you are allergic to lisinopril or to any of the excipients of the product.
- If you or a member of your family has had an allergic reaction in the past during treatment with another medicine of this group (ACE-inhibitors) that is manifested by swelling of the hands, feet or ankles, oedema of the tongue, the oral mucous membrane and/or the throat with difficulty in swallowing or breathing (angioedema).
- If your heart is severely damaged and cannot pump adequate blood or you have low blood pressure.
- If you are pregnant or you plan pregnancy.
- If you are breast-feeding.
- In children.

### Take special care when using Adipril

Tell your doctor if you have had or if you are having any health problems, especially any of the following:

- Narrowing of the aorta (aortic stenosis), narrowing of the renal artery or of the heart valves (mitral valve stenosis), increased thickness of the heart muscle (hypertrophic cardiomyopathy).
- Other health problems, such as:
  - Low blood pressure (you may feel vertigo or dizziness, especially when coming to a standing position);
  - Renal disorder or haemodialysis;
  - Liver disorder;
  - Blood vessel disorder (collagenoses), and/or treatment with allopurinol

(for gout), procainamide (for irregular heart rhythm), immunosuppressants (medicines inhibiting the immune response of the body);

- Diarrhea or vomiting;
- Diet with reduced salt intake or when taking potassium supplements.

Stop Adipril intake and immediately seek medical advice

- If you have difficulty in breathing with or without swelling of the face, the lips, the tongue and/or the throat.

- If swelling of the face, the lips, the tongue and/or the throat occurs leading to difficulty in swallowing.

- If severe itching of the skin (with raised skin rashes) occurs.

Tell your doctor if you are having or will be carrying out a desensitising treatment in case of allergy (e.g. insect biting).

Desensitising treatment reduces the allergy effects (e.g. bee and wasp biting), but sometimes may worsen the allergic reactions in case of ACE-inhibitor administration during treatment.

Tell your doctor if you will be having treatment for machine removing of cholesterol from your body (LDL apheresis).

Tell your doctor if you will be hospitalized for elective surgery. Tell your doctor or dentist that you are taking Adipril before a local or general anaesthesia will be given to you. In case of concomitant administration of Adipril with some anaesthetics, a short-term blood pressure reduction may occur soon after the tablets intake.

Take special care when taking Adipril for the first time. Upon the first intake a more pronounced blood pressure lowering than during long-term treatment may occur. This may be manifested by vertigo or dizziness and would improve in supine position.

Do not give Adipril to children under 18 years of age. Information regarding Adipril safety and efficacy in children is limited.

### Taking other medicines

Please tell your treating physician or pharmacist if you are taking or have recently taken any other medicines, including those provided over-the-counter.

Some medicines may influence the action of other medicinal products.

Discuss it with your doctor, if you are taking any of the following medicines:

- Diuretics (medicines that increase fluid elimination from the body, including potassium-sparing ones).
- Other medicines for high blood pressure (antihypertensives).
- Non-steroid anti-inflammatory drugs (NSAIDs), such as indometacin and high doses aspirin (more than 3 grams daily) that are used for treatment of arthritis and muscle aches.
- Medicines for psychiatric disorders, such as lithium, antipsychotics or tricyclic antidepressants.
- Medicines for insomnia and anxiety (hypnotics and tranquilizers).
- Potassium tablets or potassium-containing salt substitutes.
- Medicines for treatment of diabetes, such as insulin or oral medicines.
- Medicines stimulating the central nervous system (sympathomimetics). They include ephedrine, pseudoephedrine, salbutamol that may be found in some decongestants, medicines for treatment of cough, colds and asthma.
- Medicines inhibiting the immune response of the body (immunosuppressants), treatment with allopurinol (for gout) or procainamide (for irregular heart rhythm).
- Gold-containing medicines.
- Alcohol enhances the ACE-inhibitor hypotensive effect and the ACE-inhibitors enhance alcohol effect.

### Intake of Adipril with foods and drinks

There is no evidence of a need for a special diet or for limitation of certain types of foods and drinks during treatment with this product.

## Pregnancy and breast-feeding

If you are pregnant or breast-feeding or are planning to have a baby, ask your doctor or pharmacist for advice before the use of any medicine.

Adipril should not be taken during pregnancy and breast-feeding.

## Driving and using machines

At the onset of treatment with Adipril temporary dizziness, weakness, drowsiness and impaired alertness may occur, which may influence the ability for driving and using machines.

## 3. HOW TO TAKE ADIPRIL

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

For high blood pressure (arterial hypertension) the usual recommended initial dose is 10 mg once daily. The usual maintenance dose is 20 mg once daily.

For heart failure the usual recommended initial dose is 2.5 mg once daily. The usual maintenance dose is 5 up to 35 mg once daily.

For myocardial infarction the usual recommended initial dose is 5 mg on days 1 and 2 and 10 mg once daily thereafter.

For diabetes with renal complications the usual dose is 10 or 20 mg once daily.

### How to take Adipril

- Adipril tablets are for oral use and may be taken irrespective of food with adequate amount of liquid.
- The tablets should be taken once daily, preferably at the same time every day.
- If you are feeling well, do not stop your tablets unless your doctor tells you to do so.
- Remember that the first dose of Adipril may result in a more pronounced blood pressure reduction than during long-term treatment.
- If you have the feeling that Adipril effect is too weak or too strong, inform your doctor about this.

### If you take more Adipril than you should

Upon administration of a higher than the prescribed dose, immediately seek medical advice!

The overdose symptoms include severe reduction of blood pressure (dizziness or fit, loss of consciousness in more severe cases).

If inadvertently or deliberately you have taken an overdose, immediately consult your doctor or visit the emergency room of the nearest hospital.

### If you forget to take Adipril

Do not take a double dose to make up for a forgotten dose. Take it at your next regular time.

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 can cause side effects, although not everybody gets them.

Most patients do not notice any adverse reactions. Yet, if you experience any side effects, inform your doctor.

**Common adverse reactions** (in less than 1 per 10 and in more than 1 per 100 patients treated with this medicine):

Headache

Vertigo or dizziness, especially upon abrupt standing

Diarrhea

Cough

Vomiting

Adipril may affect the kidneys, which yield untypically small amount of urine or none at all.

**Uncommon adverse reactions** (in less than 1 per 100 and in more than 1 per 1,000 patients treated with this medicine):

Mood changes

Finger or toe discoloration (light blue followed by redness) and/or numbness or tingling

Taste change

Feeling of drowsiness or sleep disorder

Accelerated heart rhythm

Runny nose

Nausea

Abdominal pain or indigestion

Skin rash

Itching

Impotency

Fatigue

Weakness, asthenia

In patients with coronary disorders pronounced blood pressure lowering may occur. This may also be observed in patients with narrowing of the aorta, of the renal artery or of the heart valves or in those with increased heart muscle thickness.

**Rare adverse reactions** (in less than 1 per 1,000 and in more than 1 per 10,000 patients treated with this medicine):

**Allergic reactions:** Immediately discontinue Adipril administration and seek medical help if one of the following situations occurs:

- If you have difficulty in breathing with or without swelling of the face, the lips, the tongue and/or the throat.

- If swelling of the face, the lips, the tongue and/or the throat occurs leading to a difficulty in swallowing.

- If severe itching of the skin (with raised skin rashes) occurs.

Rarely, there may be changes in blood cells. Your doctor may sometimes take blood samples in order to check whether Adipril has any impact on your blood. Sometimes these changes may result in fatigue, throat pains or may be accompanied by high temperature, joint and muscle pains, swelling of the joints or the lymph nodes or photosensitivity.

The other rare adverse reactions are:

Confusion

Dry mouth

Hair loss

Psoriasis

Breast enlargement in males

**Very rare adverse reactions** (in less than 1 per 10,000 patients treated with this medicine):

Sinus pains

Wheezing

Lung inflammation

Yellowing of the skin and/or the eyes (jaundice)

Liver or pancreas inflammation

Severe skin disorder (its symptoms include redness, blistering and scaling)

Sweating

If any of the adverse drug reactions becomes serious or you notice other adverse reactions not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE ADIPRIL

At temperature below 30° C.

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

Do not use Adipril after the expiry date which is stated on the carton.

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. FURTHER INFORMATION

What Adipril tablets contain

**The active substance** is lisinopril dihydrate, equivalent to 5 mg, 10 mg or 20 mg lisinopril in each tablet.

The other ingredients are: lactose monohydrate; povidone; croscroscopolidone; microcrystalline cellulose; magnesium stearate.

**What Adipril tablets looks like and contents of the pack**

The tablets are white, round and flat.

The tablets are packed in blisters of PVC/aluminum foil, placed in cartons.

Adipril 5 mg tablets – 15 in a blister, 2 blisters in a box.

Adipril 10 mg tablets – 15 in a blister, 2 blisters in a box.

Adipril 20 mg tablets – 15 in a blister, 2 blisters in a box.

**Marketing Authorisation Holder and Manufacturer:**

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1700 Sofia, Bulgaria

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