PACKAGE LEAFLET: INFORMATION FOR THE USER

BERLIPRIL PLUS

10 mg + 25 mg tablets

ENALAPRIL, HYDROCHLOROTHIAZIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Berlipril PLUS is and what it is used for
2. Before you take Berlipril PLUS
3. How to take Berlipril PLUS
4. Possible side effects
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1.WHAT BERLIPRIL PLUS IS AND WHAT IT IS USED FOR

Berlipril PLUS is a medicine for lowering blood pressure (antihypertensive medicine). The combination of an ACE inhibitor (enalapril maleate, hereinafter referred to as enalapril) and medicine for enhancing urination (hydrochlorothiazide).
Berlipril PLUS is used to treat high blood pressure when it cannot only be reduced with enalapril or if you have been using the same doses of enalapril and hydrochlorothiazide, since they are now in a single tablet of Berlipril PLUS.

2. BEFORE YOU TAKE BERLIPRIL PLUS

Do not take Berlipril PLUS

- If you are allergic (hypersensitive) to the active ingredient enalapril, any other ACE inhibitor, or some of the ingredients of this medicine (listed in section 6.)
- If you are allergic (hypersensitive) to the active ingredient hydrochlorothiazide or other sulfonamide
- If you had swelling of the extremities, face, lips, throat or tongue (angioedema) during ACE inhibitor therapy

• If you have a hereditary tendency toward swelling of extremities, face, lips, throat or tongue (angioedema), or you have an unknown cause of angioedema (hereditary or idiopathic angioedema)
• If your kidney function is severely impaired (creatinine clearance below 30 ml/min) and/or going on dialysis, decreased urination
• If you have serious liver disease,
• If you are pregnant for more than 3 months (it is also better to avoid the use of medicine Berlipril Plus in early pregnancy - see section Pregnancy.)
• If you have diabetes or impaired kidney function and are treated with the medicine for lowering blood pressure containing aliskiren.

Warnings and precautions:

Talk to your doctor if you are taking any of the medicines listed below that are used to treat high blood pressure:

• Angiotensin II receptor blocker (ARB) (also called sartans – for example, valsartan, telmisartan, irbesartan), especially if you have problems with the kidney associated with diabetes.

A doctor can check your kidney function, blood pressure and the quantity of electrolytes (e.g. potassium) in the blood at regular intervals.

See also the information under the heading "don't take Berlipril PLUS".

Talk to your doctor:

• If you are at risk from excessive lowering of blood pressure because you suffer from imbalance of fluids and salts in the body, because, for example, taking medicine for excessive urination, or you are on a diet with a little salt or you have a lot of vomiting and had diarrhoea
• If your heart valves of left ventricular are narrowed, or there are other types of disorders of blood flow in the left chamber
• If you have heart disease with disturbed blood flow in the coronary arteries (heart coronary disease)
• If you have a disorder of the blood supply to the brain (cerebrovascular disease)
• If your kidney function is moderately impaired (creatinine clearance below 80 ml / min)
• If you have narrowed renal arteries (on both sides or on one side in patients with one kidney)
• If you have recently had a kidney transplant
• If you have elevated liver enzymes or you have jaundice
• If your white blood cell count drops (leukopenia), or you have significantly reduced number of leukocytes with a tendency for infection and severe general symptoms (agranulocytosis)
• If you suffer from certain diseases of connective tissue (collagen), which affects the blood vessels
• If you are using medicines that suppress your immune system
• If you simultaneously use allopurinol (for gout), procainamide (medicine for the treatment of cardiac arrhythmias), or lithium (a medicine for the treatment of certain psychiatric illness)
• If you experience hypersensitivity to the medication or start to swell (angioedema) during treatment with the medicine Berlipril PLUS
• If you have diabetes (diabetes mellitus)
• If you have gout
• If you have a persistent, dry cough
• If you are at risk from increasing the level of potassium in the blood
• If, because of your ethnic origin, the effect of lowering the pressure is not strong enough (especially in patients with black skin)

Problems such as dry mouth, thirst, weakness, heaviness, aches and pains or cramps in the muscles, rapid heartbeat, dizziness, nausea, and decreased production of urine may be a sign of disorders of fluid and mineral in the body. In this case it is necessary to inform your doctor.
If it is necessary to receive the desensitizing therapy against poison of insects (e.g. bees or wasps), Berlipril is temporarily replaced by other appropriate medicine from another class of active substances. Otherwise, you may experience hypersensitivity reactions that are life• threatening (e.g., drop in blood pressure, shortness of

breath, and vomiting, allergic reactions in the skin). These reactions may also occur after insect bites (e.g., bee or wasp).
Simultaneous use of the medicine Berlipril PLUS and dialysis with a particular high flow membranes or therapies for serious increased blood fats (LDL Apheresis with dextran sodium sulfate absorption) can cause severe reactions, all the way up to a dangerous life• threatening shock.
Before dialysis or LDL Apheresis procedures, a doctor must change the therapy in terms of introducing other suitable medicine - not an ACE inhibitor - or use another membrane with dialysis.
Tell your doctor that you are taking Berlipril PLUS, or if you need dialysis, so that a doctor can take into account relevant facts during the therapy.
In case you need to on the surgical procedure, or you need to receive anesthesia (including the one at the dentist), tell the doctor that you are taking Berlipril PLUS, as this may cause a sudden fall of blood pressure under anesthesia.

Immediately contact your doctor if you experience any of the following symptoms:

- swelling of the face, arm or leg, lips, mucous membrane, tongue and/or pharynx, staying out of breath
- yellowish skin or yellowish mucous membranes
- elevated body temperature, swollen lymph glands, and/or inflammation of the throat.

In these cases, you must immediately stop taking Berlipril PLUS and your doctor will take appropriate action.

Simultaneous use of the medicine Berlipril PLUS with lithium (a medicine to treat some psychiatric illness) is not recommended.
You must tell the doctor if you think you are (or can be) pregnant. Berlipril PLUS is not recommended in early pregnancy, and must not be used if you are pregnant longer than 3 months, because it can cause seriously harm your unborn baby during this period (see section "pregnancy").

Patients with impaired renal function
Your doctor will pay particular attention in case you have a deteriorating function of the kidneys and will begin treatment with a great caution.

Older patients
There is no evidence to suggest that one must pay special attention if the drug is administered in the elderly. Your doctor will determine the treatment in accordance with the function of your kidneys.

Children and adolescents
Berlipril PLUS is not recommended for children and adolescents under 18 years of age.

Medicine test
Contact your doctor in case you are an athlete who has to do a medicine test. Taking the medicine Berlipril PLUS can affect the result of positive anti• doping test, as it contains the active ingredient hydrochlorothiazide. The use of the medicine Berlipril PLUS as doping can harm your health.

Other medicines and Berlipril PLUS
Tell the doctor or pharmacist if you are taking or have recently taken any other medicine.

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

- if you are taking some angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Berlipril PLIUS" and "Warnings and Precautions").

Berlipril PLUS is affected by the following:
Medicines that enhance urination but keep potassium (such as spironolactone, eplerenone, triamterene or amiloride, for example), potassium supplements, salt substitute containing potassium or heparin.

Products could cause increase in potassium levels. The doctor in this case must often measure levels of potassium.
Other medicines that stimulate urination, other medicines for lowering blood pressure, medicines for the expansion of the blood vessels, medicines for depression, as well as other psychiatric illnesses (tricyclic antidepressants, antipsychotics), anesthetics, narcotics.
They can cause excessive lowering of blood pressure.

● Alcohol, barbiturates, narcotic analgesics:
They can cause a rapid fall in blood pressure when standing up from a lying position.
● Lithium (a medicine for the treatment of certain types of psychiatric illness):
There is a risk of lithium poisoning, therefore, concomitant use of medicine Berlipril PLUS and lithium is not recommended. In the event when this combination is necessary, the concentration of lithium in the blood must be carefully monitored.
● medicines for the pain and inflammation (nonsteroidal anti- inflammatory medicines):
These medicines may weaken the effects of ACE inhibitors, lead to an increase in potassium levels in the blood and a deterioration in the work of the kidneys. In rare cases there may be acute kidney failure, especially in patients with impaired renal function.

● Gold preparations (sodium aurothiomalate), a medicine in the form of injections for the treatment of rheumatism:
The possible occurrence of nitritoid reaction such as facial flushing, nausea, vomiting, decreased blood pressure.
● Medicines that suppress immune reactions (immunosuppressants), systemic corticosteroids, procainamide (anti- arrhythmic medicine):
An increased risk of a decrease in the number of leukocytes in the blood or other blood cell count (leukopenia).
● Cytostatics (e.g. cyclophosphamide, fluorouracil, methotrexate):
Increased bone marrow toxicity (especially granulocitopenia).
● medicines for the treatment of gout (eg, allopurinol, benzbromaron):
Must increase the dose for the treatment of gout.
● Sympathomimetics medicines which have a similar effect as the body's own transmitter – noradrenaline or adrenaline, (for example an increase in blood pressure), cholestyramine, and colestipol (the active substance for reducing blood fat values):
May weaken the effect on lowering blood pressure.
● Medicines for lowering blood sugar and insulin:
It may be necessary to adjust the dose of the medicine for lowering blood sugar or insulin.
● Amphotericin B (the active substance for the treatment of fungal diseases) carbenoxolone (the active substance for the treatment of gastric ulcer in the stomach or intestines), medicines that contain cortisone (corticosteroids), a corticotrophin- (a hormone that acts on the adrenal glands), potassium• sparing diuretics (some types of medicines that increase the excretion of urine for example, furosemide, or certain laxatives:
Disorder in respect of minerals in the body, for example, reduced the level of potassium.
● Calcium Salts:
An increased level of calcium in the blood.
● Cardiac glycosides (e.g., digoxin, active substance for the strengthening of the stroke volume of the heart):
Increased activity and increased adverse reactions in cardiac glycosides.
● Muscle relaxants (e.g., tubocurarine chloride, the active substance for muscle relaxation):
Excessive and prolonged action of medicines for muscle relaxation.
● Medicines that can cause "torsades de pointes", a dangerous type of heart rhythm disorders (e.g., certain medicines for the treatment of heart rhythm disorders, such as quinidine, procainamide, amiodarone, or sotalol psychoactive medicines):
An increased risk of the appearance of "torsades de pointes" due to the decrease in the level of potassium in the blood.

Berlipril PLUS taken with food, non- alcoholic drink and alcohol
● Alcohol: increases the effect of lowering of blood pressure

Pregnancy and breastfeeding

If you are pregnant or breast- feeding, you think you are pregnant or planning to get pregnant, contact your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You must tell the doctor if you think you are (or can be) pregnant.
A doctor will advise you to stop taking Berlipril PLUS before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of the medicine Berlipril PLUS. Berlipril PLUS is not recommended in early pregnancy, and must not be used if you are pregnant longer than 3 months, because it can cause serious harm to your unborn baby during this period.

Breast feeding
Contact your doctor if you are breast- feeding or need to start to breastfeed. Breast• feeding is not recommended while you are taking Berlipril PLUS.

Driving and using machines

Berlipril PLUS may affect the ability to participate in traffic or operate machinery. This applies especially to the beginning of treatment, when increasing dose or changes in the composition, or if the medicine is used in combination with alcohol. There may be dizziness or fatigue.

Berlipril PLUS contains lactose.

This medicine contains lactose. If your doctor said you have intolerance to some sugars, contact your doctor for advice before taking this medicine.

3. HOW TO TAKE BERLIPRIL PLUS

Always take Berlipril PLUS exactly as your doctor has prescribed. If you are not sure, contact your doctor or pharmacist for advice.

Your doctor will probably first adjust the dose of the individual active substances of medicine Berlipril PLUS (enalapril and hydrochlorothiazide). If it is justified, the doctor may order a direct transition from the two individual therapies to Berlipril PLUS combination.
The recommended daily dose is 1 Berlipril PLUS tablet.

Note:
When you switch between the two individual substances on their combination it may cause an excessive drop in blood pressure. This applies especially to patients who have a lack of salt and / or fluid in the body (e.g., after vomiting, diarrhea, or previous administration of the drug for promoting urination) as well as in patients with severe heart failure or severe hypertension, or high blood pressure caused by renal disease. After taking the first Berlipril PLUS tablets, you will probably be under close medical supervision to 8 hours.

Method of Administration:

Berlipril PLUS can be taken regardless of the meal. The daily dose should be taken in the morning with a lot of fluids (for example, a glass of water).
The division line is here to help you. In the event that you cannot swallow the whole tablet, divide it by the division line and take it with water.

The duration of therapy

The doctor will determine the length of the duration of therapy. Therapy with medicinal product Berlipril PLUS is usually long- lasting.
Contact the doctor or pharmacist if you think the effect of the medicine Berlipril PLUS is too strong or too weak.

If you take more medicine Berlipril PLUS than you should

If you accidentally take more tablets than you should, immediately contact a doctor/emergency service. They will decide on the necessary measures based on the severity of poisoning.
Depending on the amount of a medicine overdose, one or more of the following symptoms are possible:
Increased urination, disorder of minerals in the body, drop in blood pressure, impaired consciousness, all the way to the deep unconsciousness, cramps, mild paralysis, accelerated or slowed heart rate, strong heart beats, circulatory shock and kidney failure.
In the case of a suspected overdose, you must immediately seek the help of doctor.

If you forget to take Berlipril PLUS

Do not take a double dose to make up for the missed dose.

If you stop taking Berlipril PLUS

Don't stop the therapy with Berlipril PLUS on your own without consulting your doctor.
In case you have additional questions about the use of this medicine, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, it may cause side effects although not everybody gets them. If you have serious side effects, as well as those that are not listed in this leaflet, contact the doctor or pharmacist.

Significant side effects or signs on which you have to pay attention, and the measures to be taken in this case:
Swelling of the tissue (edema, angioneurotic) that takes over the larynx, part of the larynx credited for speech and/or language requires prompt treatment with doctors in an emergency room.
If you notice signs of jaundice, you need to stop treatment and contact the doctor.
In the case of an elevated body temperature, swollen lymph glands and/or inflammation of the throat, immediately contact your doctor to control blood cells.
Immediately contact your doctor in case of the above side effects.

Other possible side effects

Very common (more than 1 in 10 people):

- blurred vision
- Vertigo
- Cough
- Feeling sick (nausea)
- Weakness

Common (up to 1 in 10 people):

- Depression
- Loss of consciousness, headache
- Excessively low blood pressure, including a sudden drop when getting up from a lying position, disturbances of the heart rhythm (irregular heart beat), feeling the tightening in her chest (angina pectoris), rapid heartbeat (tachycardia), palpitations
- Shortness of breath
- Diarrhea, pain in the abdomen, taste disturbance,
- Rash, hypersensitivity/swelling of the tissues (edema, angioneurotic)

• Muscle spasms
• Fatigue, pain in the chest
• Increased level of potassium, uric acid and/or and creatinine in the blood, increasing the levels of fats in the blood (cholesterol and triglycerides), low level of potassium in the blood

Less common (up to 1 in 100 people):
• Anemia due to increased deterioration of red blood cells (hemolytic anemia), a disorder of creation of blood cells in the bone marrow (aplastic anemia)
• Too low blood sugar (hypoglycemia)
• Confusion, sleepiness, insomnia, nervousness, abnormal sensations (e.g. tingling, tingling, pricking), Vertigo
• You see yellow
• Ringing in the ears (Tinnitus)
• Redness of the face, a heart attack or stroke, probably as a result of the lowering of blood pressure at risk patients (patients with a disorder of the blood flow to the area of the heart and/or brain)
• Heart palpitations
• Runny nose, sore throat and hoarseness, narrowing of the bronchial• like cramps, asthma
• Obstruction of the bowel disorder, vomiting, dry mouth, indigestion, ulcers on the stomach, bloating, constipation, stomach irritation, inflammation of the pancreas
• increased sweating, itching, hives, loss of hair, skin sensitivity to light
• Joint pain (arthralgia)
• Disorder of the kidney, renal failure, increased excretion of protein in the urine
• Impotence
• Decrease of sodium in the blood, a drop in value of magnesium, an increase in the value of urea
• Gout
• Decreased libido

Rare (up to 1 in 1000 people):
• Inflammation of the salivary glands
• reduction in the number of certain blood cells (leukopenia, neutropenia, thrombocytopenia, pancytopenia) to a serious decrease in blood cells with a tendency towards infection and serious general symptoms(agranulocytosis), a decline of certain laboratory values (hemoglobin and hematocrit), weakened the function of bone marrow (bone marrow depression), swollen lymph glands, autoimmune diseases
• sleep disorders
• Circulatory disturbance in the hands and feet caused by spasms of the blood vessels (Raynaud's syndrome), inflammation of the small blood vessels
• Abnormalities in lung tissue (pulmonary infiltrates), respiratory disorder (including pneumonitis and pulmonary edema) of the nose that is leaking, allergic inflammation of the lungs (allergic alveolitis/eosinophilic pneumonia)
• Inflammation of the mouth with the boils (stomatitis/mouth ulcers), inflammation of the mucous membrane of the tongue
• Liver failure, the deterioration of liver cells (hepatic necrosis – can be fatal), inflammation of the liver (hepatitis), inflammation of the gallbladder (cholecististis), especially in patients with a history of heolelitiazom jaundice
• Severe skin reactions (erythema multiform, Stevens – Johnson syndrome, exfoliative dermatitis, Toxic Epidermal Necrolysis, Pemphigus, Erythroderma or), skin reactions similar to erythematous skin, Lupus (a particular type of autoimmune disease that grips the skin), relapse, erythematous Cutaneous Lupus, severe reactions, hypersensitive dotted the bleeding under the skin (purpura)
• Reduced urination
• Breast enlargement in men
• Increased the value of the liver (liver enzymes, bilirubin), increased blood sugar, sugar in the urine
• Acute inflammation of the kidney

• Partial loss of movement (paresis), due to low potassium

Very rare (up to 1 in 10 000 people):

• Increase in the pH of the blood, the increased value of calcium in the blood
• Swelling of the tissue of the intestine (intestinal angioneurotic edema)

Unknown (frequency cannot be determined on the basis of the available data):

• Syndrome of antidiuretic hormone (SIADH) that results in low values of sodium in the blood (symptoms can be tiredness, headache, nausea, vomiting) a complex syndrome can follow some or all of the above side effects: high temperature, inflammation of the serous membrane (lung tissues), inflammation of the blood vessels, muscle pain/joint pain and inflammation of the joints, certain changes in laboratory values (positive ANA titer, increased sedimentation, Eosinophilia and Leukocytosis), skin rashes, sensitivity to light or other skin reactions.

If you have any of the above side effects, contact your doctor, or pharmacist. This implies to the occurrence of adverse reactions that are not listed in this manual.

5. HOW TO STORE BERLIPRIL PLUS

Keep out of reach of children!
Do not use this medicine after the expiry date stated on the blister and the box under "EXP". The expiry date refers to the last day of the month.
Medicines should not be disposed of as normal household drains. Ask your pharmacist how to throw away medicines that you no longer need. These measures help to protect the environment.
Keep at temperature up to 30 ° c.
Store in the original packaging to protect the medicine from moisture.

6. FURTHER INFORMATION

What Berlipril PLUS contains

Active compounds are enalapril maleate and hydrochlorothiazide.
Each tablet contains 10 mg of enalapril maleate and 25 mg of hydrochlorothiazide.
The other ingredients are: monohydrating lactose, magnesium carbonate light, gelatin, sodium starch glycolate (type A), colloidal anhydrous silica, magnesium stearate, iron oxide hydrate, yellow color (E 172)

How Berlipril PLUS looks like and contents of the Pack

Light yellow, round tablets, straight on both sides with bevelled ends and dividing line on one side.
Berlipril PLUS is available in packs of 30 tablets.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Berlin- Chemie AG (Menarini group)
Glienicker Weg 125
12489 Berlin
Germany

Manufacturer of the medicinal product

Berlin- Chemie AG (Menarini group)
As Glienicke Weg 125
12489 Berlin, Germany