

PACKAGE LEAFLET: INFORMATION FOR THE USER

BERLIPRIL

5 mg, 10 mg, 20 mg TABLETS

ENALAPRIL MALEATE

• 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 Tablets are and what they are used for
2. Before you take Berlipril Tablets
3. How to take Berlipril Tablets
4. Possible side effects
5. How to store Berlipril Tablets

1. WHAT BERLIPRIL TABLETS ARE AND WHAT THEY ARE USED FOR

Berlipril Tablets belong to a group of medicines called 'ACE inhibitors' (angiotensin converting enzyme inhibitors).

Berlipril Tablets are used

- to treat high blood pressure (hypertension).
- to treat heart failure (weakening of heart function). It can lower the need to go to hospital and can help some patients live longer.
- to prevent the signs of heart failure. The signs include: shortness of breath, tiredness after light physical activity such as walking, or swelling of the ankles and feet.

Enalapril works by widening your blood vessels. This lowers your blood pressure. The medicine usually starts to work within an hour, and the effect lasts for at least 24 hours. Some people will require several weeks of treatment until the best effect on your blood pressure is seen.

2. BEFORE YOU TAKE BERLIPRIL TABLETS

Do not take Berlipril Tablets if:

- you are allergic (hypersensitive) to enalapril maleate or any of the other ingredients of Berlipril Tablets or to any other ACE inhibitors similar to Enalapril tablets.

- you ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited.
- you are more than 3 months pregnant. (it is also better to avoid Berlipril Tablets in early pregnancy- see pregnancy section.)

Do not take Berlipril Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Berlipril Tablets.

Take special care with Berlipril Tablets

Check with your doctor or pharmacist before taking Berlipril Tablets if any of the following apply to you.

- If you think you are (or might become) pregnant. Enalapril Tablet is not recommended 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 at that stage (see pregnancy section).
- If you are breast-feeding or about to start breast-feeding (see breast-feeding section).
- If you have a kidney problem (including kidney transplantation). These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of Berlipril Tablets or monitor your blood level of potassium.
- If you are having dialysis.
- If you have been very sick suffered from excessive vomiting or had bad diarrhoea recently.
- If you are on a salt-restricted diet, are taking potassium supplements, potassium- sparing agents, or potassium-containing salt substitutes.
- If you are over 70 years of age.
- If you have a heart problem.
- If you have a condition involving the blood vessels in the brain.
- If you suffer from blood problems such as low or lack of white blood cells (neutropenia / agranulocytosis), low blood platelet count (thrombocytopenia) or a decreased number of red blood cells (anaemia).
- If you have a liver problem.
- If you have collagen vascular disease (e.g. lupus erthematosus, rheumatoid arthritis or scleroderma), are on therapy that suppress your immune system, are taking drugs like allopurinol(used for the treatment of gout) or procainamide(used to treat abnormal heart rhythms) or any combinations of these. Your doctor may periodically take a blood sample to check your white cell count. If any of these apply to you and you develop an infection (symptoms may be high temperature, feverish), you should let your doctor know immediately.
- If you have a history of angioedema (symptoms such as itching, nettle rash, wheezing or swelling of the hands, throat, mouth and eye lids) while taking other medicines.You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- If you have low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- If you have diabetes and are taking antidiabetic agents or insulin to control your diabetes; you should closely monitor your blood for low blood glucose levels especially during the first month of treatment. The level of potassium in your blood can also be higher.

You should be aware that Berlipril Tablets lowers the blood pressure in black patients less effectively than in non-black patients.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Berlipril Tablets.

Please let your doctor know immediately if you develop any of the following symptoms while taking Berlipril Tablets

- Jaundice (yellowing of the skin and whites of the eyes)
- A dry cough which is persistent for a long time

If you going to undergo any of the below mentioned procedures, please tell the doctor who is treating you that you are taking Berlipril Tablets.

- a treatment called LDL apheresis, which is removal of cholesterol from your blood.
- a desensitisation treatment to reduce the effect of an allergy to bee or wasp stings.
- any surgery or receive anaesthetics (even at the dentist).

If any of the above applies to you, talk to your doctor or dentist before the procedure.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to lower blood pressure, such as beta-blockers, prostaglandins, nitrates (e.g. nitroglycerin) or water tablets (diuretics).
- Medicines containing potassium (including dietary salt substitutes).
- Medicines for diabetes (including oral antidiabetic medicines and insulin).
- Medicine used to treat a certain kind of depression (e.g. lithium)
- Medicines for depression called 'tricyclic antidepressants'. (e.g. Amitriptyline)
- Medicines for mental problems called 'antipsychotics'. (e.g. Haloperidol, Chlorpromazine)
- Certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'. (e.g. Ephedrine)
- Certain pain or arthritis medicines including gold therapy.
- Non-steroidal anti-inflammatory drugs, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)(e.g. Aspirin (acetylsalicylic acid, Ibuprofen).
- Medicines used to dissolve blood clots (thrombolytics).
- Alcohol.
- Medicines used to treat hyperacidity (antacids)
- Medicines used to treat auto-immune disorders (such as rheumatoid arthritis) or given after transplant surgery (e.g. ciclosporin). These are called immunosuppressants.
- Medicine used to treat anaemia, commonly associated with chronic renal failure and cancer chemotherapy (e.g. Epoetin)
- Medicines used to treat birth control or given in estrogen replacement therapy for post- menopausal women e.g. Oestrogens
- Medicines used to treat Parkinson's disease (e.g. levodopa),
- Medicines used to treat erectile dysfunction (e.g. moxislyte),
- Medicines used for the treatment of spastic movement disorders (e.g. baclofen)
- Medicines used for the treatment of spasms, cramping, and tightness of muscles (e.g. tizanidine).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Berlipril Tablets.

Taking Berlipril Tablets with food and drink

Berlipril Tablets can be taken with or without food. Most people take Berlipril Tablets with a drink of water.

Preganancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Berlipril Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Berlipril Tablets. Berlipril Tablets is not recommended in early

pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

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

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding new born babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Berlipril Tablets. In case of an older baby your doctor should advise you on the benefits and risks of taking Berlipril Tablets whilst breast-feeding, compared to other treatments. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel dizzy or sleepy while taking Berlipril Tablets. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Berlipril Tablets

These tablets contain Lactose. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking Berlipril Tablets.

3. HOW TO TAKE BERLIPRIL TABLETS

Always take Berlipril Tablets exactly as your doctor as told you. You should check with your doctor or pharmacist if you are not sure. The dose you take will depend on your condition and whether you are taking any other treatment. The usual dose is:

High Blood Pressure

- The usual starting dose ranges from 5 to 20 mg taken once a day.
- Some patients may need a lower starting dose.
- The usual long term dose is 20 mg taken once a day.
- The maximal long term dose is 40 mg taken once a day.

Heart Failure

- The usual starting dose is 2.5 mg taken once a day.
- Your doctor will raise this amount step by step until the dose that is right for you has been achieved.
- The usual long term dose is 20 mg each day, taken in one or two doses.
- The maximal long term dose is 40 mg each day, divided in two doses.

Patients with kidney problems

Your dose of medicine will be changed depending on how well your kidneys are working:

- Moderate kidney problems - 5 mg to 10 mg each day.
- Severe kidney problems - 2.5 mg each day.
- If you are having dialysis - 2.5 mg each day. On days you are not having dialysis, your dose may be changed depending on how low your blood pressure is.

Elderly patients

Your dose will be decided by your doctor, and will be based on how well your kidneys are working.

Children

Use of Berlipril Tablets in children with high blood pressure is limited. If the child can swallow tablets, the dose will be worked out using the child's weight and blood pressure. The usual starting doses are:

- between 20 kg and 50 kg – 2.5 mg each day.
- more than 50 kg – 5 mg each day.

The dose can be changed according to the needs of the child:

- a maximum of 20 mg daily can be used in children who are between 20 kg and 50 kg.
- a maximum of 40 mg daily can be used in children who are more than 50kg.

Berlipril Tablets is not recommended in new-born babies (first few weeks after birth) and in children with kidney problems.

If you take more Berlipril Tablets than you should

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

The following effects may happen: feeling of light-headed or dizziness. This is due to a sudden or excessive drop in blood pressure.

If you forget to take Berlipril Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Berlipril Tablets

Do not stop taking your medicine unless your doctor tells you to.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Berlipril Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects: Please STOP taking Berlipril Tablets and go to a doctor immediately, if you experience any of the following side effects:

- Severe dizziness or light-headedness,
- Itching or rash,
- Blistering of the skin, mouth, eyes or genitals,
- Swelling of the hands, feet, mouth, lips, tongue, throat or face(Afro Caribbean patients may have a higher risk of this side effect),
- Shortness of breath or wheezing,
- Pain or tightness in the chest, neck, shoulders or arms,
- Numbness or weakness on one side of the body (e.g. a dropping arm, leg or lower eyelid, or a dribbling mouth),
- Slurred speech and /or blurred vision,
- Confusion or unsteadiness,
- Pancreatitis-symptoms include abdominal pain, nausea,
- Difficulty in breathing due to build up of fluid in the lungs,
- Heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain),
- Stroke (possibly due to very low blood pressure in high-risk patients),
- Stevens-Johnson syndrome' a serious skin condition where you have reddening and scaling of your skin, blistering or raw sores, or detachment of the top layer of skin from bottom layers,

- Liver problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), higher levels of liver enzymes or bilirubin (measured in a blood test).

Other side effects include:

Very Common (affects more than 1 in 10 people)

- Feeling dizzy, weak or sick.
- Cough.

Common (affects less than 1 in 10 people)

- Low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain.
- Headache, fainting (syncope),
- Change in sense of taste,
- Diarrhoea,
- Tiredness (fatigue), depression,
- Increased blood potassium level, increased levels of creatinine in your blood (both are usually detected by a test).

Uncommon (affects less than 1 in 100 people)

- Sudden fall in blood pressure,
- Fast or uneven heart beats (palpitations),
- Anaemia (including aplastic and haemolytic),
- Confusion, sleeplessness or sleepiness, nervousness,
- Pins and needles,
- Vertigo,
- Ringing in your ears (tinnitus),
- Runny nose, sore throat or hoarseness,
- Asthma,
- Slow movement of food through your intestine,
- Being sick (vomiting), indigestion, constipation, anorexia,
- Irritated stomach (gastric irritations), dry mouth, ulcer,
- Increased perspiration,
- Loss of hair,
- Muscle cramps, flushing, generally feeling unwell (malaise), high temperature (fever), Impotence,
- High level of proteins in your urine (measured in a test),
- Low level of blood sugar or sodium, high level of blood urea (all measured in a blood test).

Rare (affects less than 1 in 1,000 people)

- 'Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow,
- Changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets,
- Bone marrow depression,
- Autoimmune diseases,
- Strange dreams or sleep problems,
- Pulmonary infiltrates,
- Inflammation of your nose,
- Pneumonia,
- Inflammation of the cheeks, gums, tongue, lips, throat,
- Lower amount of urine produced,
- Erythema multiforme,
- Enlargement of the mammary glands in males.

Very Rare (affects less than 1 in 10,000 people)

- Swelling in your intestine (intestinal angioedema).

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

5. HOW TO STORE BERLIPRIL TABLETS

- Do not store above 25°C. Store in the original package.
- Keep out of the reach and sight of children.
- Do not use your tablets after the expiry date stated on the label or carton.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last approved in {07/2012}.