

PACKAGE LEAFLET: INFORMATION FOR THE USER

ENALAPRIL HCT

20mg/12.5mg tablets

ENALAPRIL MALEATE/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 Enalapril HCT is and what it is used for
2. What you need to know before you take Enalapril HCT
3. How to take Enalapril HCT
4. Possible side effects
5. How to store Enalapril HCT

1. WHAT ENALAPRIL HCT IS AND WHAT IT IS USED FOR

Enalapril HCT contains enalapril maleate and hydrochlorothiazide:

- enalapril belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACE inhibitors), which work by widening your blood vessels
- hydrochlorothiazide belongs to a group of medicines known as water tablets (diuretics), which increase the volume of urine you produce.

The effect of these medicines is to lower your blood pressure. Enalapril HCT is used to treat high blood pressure (hypertension). Taking both medicines that Enalapril HCT contains can increase their effect compared to taking just one.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENALAPRIL HCT

Do not take Enalapril HCT:

- if you are allergic to enalapril maleate, hydrochlorothiazide, or any of the other ingredients of this medicine.

- if you have previously been treated with a medication in the same group of drugs as this medicine (ACE inhibitors) and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing. You should not take this medicine if you have had these types of reactions without a known cause, or if you have been diagnosed with hereditary or idiopathic angioedema.
- if you are allergic to any sulfonamide-derived drugs. (Ask your doctor if you are not sure what sulfonamide-derived drugs are.)
- if you are not passing urine
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

- if you are more than 3 months pregnant. (It is also better to avoid Enalapril HCT in early pregnancy – see pregnancy section.)
- if you have a condition known as renal artery stenosis (narrowing of the arteries that supply the blood to your kidneys)
- if you have severe kidney or liver problems

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

Warning and precautions

Talk to your doctor or pharmacist before taking Enalapril HCT

- if you have kidney problems, have had a recent kidney transplantation, are a dialysis patient, or are taking water tablets (diuretics)
- if you have blood disorders or liver problems
- if you are on a salt restricted diet, or have suffered from excessive vomiting or diarrhoea recently
- if you have a heart condition called ‘aortic stenosis’, ‘hypertrophic cardiomyopathy’ or ‘outflow obstruction’
- if you have collagen vascular disease, are taking immunosuppressant therapy (used for the treatment of autoimmune disorders such as rheumatoid arthritis or following transplant surgery)
- if you are taking allopurinol, (used for the treatment of gout), or procainamide, (used to treat abnormal heart rhythms). If you develop an infection (symptoms may be high temperature or fever), you should let your doctor know immediately. Your doctor may take a blood sample from time to time to check your white blood cell count
- if you have a history of ‘angioedema’ while taking other medicines. The signs may have been itching, nettle rash, wheezing or swelling of your hands, throat, mouth or eyelids
- if you have diabetes and are taking antidiabetic medicines, including insulin to control your diabetes (you should monitor your blood for low blood glucose levels, especially during the first month of treatment)
- if you are taking potassium supplements or potassium containing salt substitutes
- if you are taking lithium, used for the treatment of some psychiatric illnesses
- if you have been told by your doctor that you have an intolerance to some sugars.
- if you think you are (or might become) pregnant. This medicine 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).
- tell your doctor if you are taking either of the following medicines used to treat high blood pressure:

- an angiotensin II receptor blocker (ARB) (also known as sartans – for example valsartan, telmisartan, irbesartan etc), 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 information under the heading “Do not take Enalapril HCT.”

If you are about to have any of the following procedures, you should tell your doctor who is treating you that you are taking Enalapril HCT:

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

Routine tests

When you first start to take Enalapril HCT, your doctor will monitor your blood pressure frequently to ensure you have been given the correct dose. In addition, for some patients the doctor may want to do some tests to measure your potassium, sodium, magnesium, creatinine and liver enzyme levels. Tell your doctor if you have or will take an anti-doping test since this medication can produce a positive result.

Children and adolescents

Enalapril HCT is not recommended for use in children.

Other medicines and Enalapril HCT

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. Your doctor may need to change your dose and/or to take other precautions.

In general, Enalapril HCT can be taken with other drugs. For prescribing the correct dose of Enalapril HCT, it is especially important for your doctor to know whether you are taking any of the following medicines:

- an angiotensin II-receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Enalapril HCT” and “Warnings and precautions”),
- potassium sparing water tablets (diuretics) such as spironolactone, eplerenone, triamterene or amiloride, potassium supplements, or potassium-containing salt substitutes. Enalapril HCT may increase the levels of potassium in your blood leading to high potassium levels. This causes few signs and is usually seen by a test,
- water tablets (diuretics) such as thiazides, furosemide, bumetanide,
- other medicines that lower blood pressure, such as nitroglycerine, nitrates, and vasodilators,
- lithium, used for the treatment of some psychiatric illnesses. Enalapril HCT should not be taken with this drug
- barbiturates (sedatives used for sleeplessness or epilepsy),
- tricyclic antidepressants such as amitriptyline, used for depression, antipsychotics such as phenothiazines, used for severe anxiety,
- pain killers such as morphine or anaesthetics, because your blood pressure may become too low,
- cholestyramine or colestipol (used to help control cholesterol levels),
- medicines used for, stiffness and inflammation associated with painful conditions, particularly those affecting your muscles, bones and joints:
 - including gold therapy which can lead to flushing of your face, feeling sick (nausea), vomiting and low blood pressure, when taken with Enalapril HCT, and

- non-steroidal anti-inflammatory drugs (NSAIDs), for example diflunisal or diclofenac. They may prevent your blood pressure from being well controlled and may increase the level of potassium in your blood

- medicines such as ephedrine, used in some cough and cold remedies, or noradrenaline and adrenaline used for low blood pressure, shock, cardiac failure, asthma or allergies. If used with Enalapril HCT these drugs may keep your blood pressure high,
- ACTH (to test whether your adrenal glands are working properly),
- corticosteroids (used to treat certain conditions such as rheumatism, arthritis, allergic conditions, asthma or certain blood disorders),
- allopurinol (used to treat gout),
- ciclosporins (immunosuppressive agents used for autoimmune disorders),
- medicines for the treatment of cancer,
- antacids (used for indigestion relief),
- procainamide, amiodarone or sotalol (used to treat abnormal heart rhythms),
- digitalis (used to treat heart rhythm problems),
- carbenoxalone (used to treat stomach ulcers),
- excessive use of laxatives,
- antidiabetic medicines such as insulin. Enalapril HCT may cause your blood sugar levels to drop even further if you take it with antidiabetics
- an mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus) as coadministration could increase the risk for an allergic reaction called angioedema.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Enalapril HCT.

Enalapril HCT with food, drink and alcohol

Most people take Enalapril HCT with a drink of water.

Enalapril HCT can be taken with or without food. However, if you drink alcohol while taking Enalapril HCT, it may cause your blood pressure to drop too much and you may experience dizziness, light-headedness or faintness. You should keep your alcohol intake to a minimum.

Pregnancy and breast-feeding

Pregnancy

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. Your doctor will normally advise you to stop taking Enalapril HCT before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enalapril HCT. This medicine is not recommended during 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. This medicine is not recommended for mothers who are breast-feeding.

Driving and using machines

Certain side effects, such as dizziness and weariness, have been reported with this medicine which may affect some patients' ability to drive or operate machinery (see Possible side effects).

Enalapril HCT contains lactose

Enalapril HCT contains lactose, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE ENALAPRIL HCT

Taking this medicine

- You should take this medicine by mouth.
- Always take this medicine exactly as your doctor or pharmacist has told you.
- The number of tablets you take each day will depend upon your condition. Check with your doctor or pharmacist if you are not sure.

REMEMBER, this medicine is for you. Do not share it with anyone else. It may not suit them.

The recommended dose is:

- One tablet each day.
- Your doctor may increase the dose to two tablets each day.
- Do not take more or less than your doctor has prescribed.

If you take more Enalapril HCT than you should

Contact your doctor immediately if you think you have taken more of your tablets than you should. The most common signs and symptoms of an overdose are a fall in blood pressure and stupor (a state of almost complete lack of consciousness). Other symptoms may include dizziness or light-headedness due to a fall in blood pressure, forceful and rapid heartbeat, rapid pulse, anxiety, cough, kidney failure, and rapid breathing.

If you forget to take Enalapril HCT

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Enalapril HCT

Do not stop taking your medicine, unless your doctor tells you to. If you do your blood pressure may increase. If your blood pressure becomes too high it may affect your heart and kidneys.

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. The following side effects may happen with this medicine:

It is vital to stop taking Enalapril HCT and seek medical attention immediately if you begin to have the following symptom:

- allergic reaction - you may get an itch, short of breath or wheezy and develop swelling of your hands, mouth, throat, face or eyes.

Stop taking Enalapril HCT immediately and see your doctor if you have any of the following side effects

- severe dizziness, light-headedness, especially at the start of treatment or when your dose is increased or when you stand up.

Other possible side effects

Very common (affects more than 1 in 10 people)

- blurred vision, cough, feeling sick (nausea), weakness

Common (affects less than 1 in 10 people)

- headache, depression, low blood pressure, fainting (syncope)
- chest pain, heart rhythm changes, angina or chest pain, fast heart beat, shortness of breath
- diarrhoea, pain around your stomach area (abdomen), changes in taste, fluid retention (oedema), feeling tired
- rash, hypersensitivity/angioneurotic oedema: angioneurotic oedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported
- increased blood potassium level, increases in serum creatinine (both are usually detected by a test); low levels of potassium in the blood, increased levels of cholesterol, increased levels of triglycerides, increased levels of uric acid in the blood
- muscle cramps

Uncommon (affects less than 1 in 100 people)

- anaemia (including aplastic and haemolytic), anxiety, a sense of heightened awareness or a shaky feeling (caused by low blood sugar), confusion, feeling sleepy, difficulty sleeping, feeling nervous, tingling or numbness, feeling like you are spinning (vertigo)
- low blood pressure (which may make you feel dizzy when you stand up), fast or uneven heart beats (palpitations), heart attack or stroke (in high risk patients)
- runny nose, sore throat and hoarseness, difficulty breathing or asthma
- slow movement of food through your intestine (ileus), pancreatitis, being sick, indigestion, constipation, not feeling like eating properly (anorexia), stomach irritation, dry mouth, flatulence, gout
- burning, aching pain with an empty feeling and hunger, particularly when the stomach is empty (caused by a peptic ulcer), increased sweating, itching, hives (urticaria), hair loss, protein in your urine (usually detected by a test)
- impotence, decreased libido, flushing, ringing in your ears, feeling lethargic, high temperature
- increases in blood urea and decreases in blood sodium levels (usually detected by a test), feeling unwell (malaise)
- low level of magnesium in the blood (hypomagnesaemia)
- kidney problems
- joint pain

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

- strange dreams, sleep problems
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, swollen glands in neck, armpit or groin
- swollen glands, autoimmune diseases, low blood flow to your fingers and toes causing redness and pain (Raynaud's), accumulation of fluid or other substances in the lungs (as seen on X-rays), runny or sore nose
- eosinophilic pneumonia (signs may be cough, high temperature and difficulty breathing)
- pain, swelling or ulcers in your mouth, infection or pain and swelling of your tongue, kidney problems such as lower back pain and reduction in the volume of urine you pass
- inflammation of the nose
- difficulty breathing, respiratory distress
- liver failure or hepatitis, this may cause yellowing of your skin (jaundice), gall bladder problems
- severe hypersensitivity reaction with high fever, skin rash that looks like targets (erythema multiforme), Stevens-Johnson syndrome and toxic epidermal necrolysis (severe skin conditions with reddening, scaling and blistering of the skin), severe skin rash with loss of skin and hair (exfoliative dermatitis), cutaneous lupus erythematosus (an immune disease), red rash with peeling of the skin (erythroderma), small fluid-filled bumps on the skin (pemphigus), purple or red spots on the skin (purpura)
- development of breasts in men

- increased liver enzymes or blood 'bilirubin' (usually detected by a blood test), increases in blood sugar
- muscle weakness, sometimes due to low potassium (paresis)

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

- swelling in your intestine (intestinal angioedema). Signs may include stomach pain, feeling sick and vomiting, elevated calcium level in blood

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

A complex side effect has also been reported which may include some or all of the following signs:

- fever, inflammation of your blood vessels, pain and inflammation of muscles or joints
- blood disorders affecting the components of your blood (usually detected by a blood test)
- rash, hypersensitivity to sunlight and other effects on your skin
- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ENALAPRIL HCT

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original container.

Do not put this medicine into another container as it might get mixed up.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the 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.

This leaflet was last revised in October 2015

This leaflet gives you some of the most important patient information about Enalapril HCT. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.