Package leaflet: Information for the user

Enap 5 mg, 10 mg & 20 mg Tablets

enalapril maleate

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. See section 4.

What is in this leaflet

1 What Enap is and what it is used for

Enap contains an active substance called enalapril maleate. This belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

Enap is 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.

Enap 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 What you need to know before you take Enap

Do not take Enap if:
- you are allergic to enalapril maleate or any of the other ingredients of this medicine (listed in section 6)
- you have ever had an allergic reaction to a type of medicine similar to Enap called an ACE inhibitor
- you have 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 Enap in early pregnancy – see Pregnancy section)
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

• you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Enap if:
• you have a heart problem
• you have a condition involving the blood vessels in the brain
• you have a blood problem 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)
• you have a liver problem
• you have a kidney problem. These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of Enap or monitor your blood level of potassium.
• you have had a kidney transplant
• you are having dialysis
• you have been very sick (excessive vomiting) or had bad diarrhoea recently
• you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, or potassium-containing salt substitutes
• you are over 70 years of age
• you have diabetes. You should 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 have ever had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
• you have low blood pressure (you may notice this as faintness or dizziness, especially when standing)
• you have collagen vascular disease (e.g. lupus erythematosus, rheumatoid arthritis or scleroderma), are on therapy that suppresses your immune system, are taking the drugs allopurinol or procainamide, or any combination of these
• you are taking any 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 Enap if'.
• you think you are (or might become) pregnant. Enap 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).
• you are breast-feeding or about to start breast-feeding (see Breast-feeding section).

If you are taking any of **the following medicines**, the risk of angioedema may be increased:
• racecadotril, a medicine used to treat diarrhoea;
● medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
● vildagliptin, a medicine used to treat diabetes.

You should be aware that Enap 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 Enap.

If you are about to have a procedure
If you are about to have any of the following, tell your doctor that you are taking Enap:
• any surgery or receive anaesthetics (even at the dentist)
• a treatment to remove cholesterol from your blood called 'LDL apheresis'
• a desensitisation treatment, to lower the effect of an allergy to bee or wasp stings.
If any of the above applies to you, talk to your doctor or dentist before the procedure.

Other medicines and Enap
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Enap can affect the way some medicines work. Also some other medicines can affect the way Enap works.

This applies in particular if you are also taking:
• other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics)
• medicines for diabetes (including oral antidiabetic medicines and insulin)
• lithium (a medicine used to treat a certain kind of depression)
• medicines for depression called 'tricyclic antidepressants'
• medicines for mental problems called 'antipsychotic'
• certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'
• 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)
• aspirin (acetylsalicylic acid)
• medicines used to dissolve blood clots (thrombolytics)
• sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults (see section 2 'Do not take Enap')
● vildagliptin, a medicine used to treat diabetes
• racecadotril, a medicine used to treat diarrhoea
• medicines which are most often used to avoid rejection of transplanted organs (sirolimus, temsirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions"

In particular, talk to your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:
● potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).

Your doctor may need to change your dose and/or to take other precautions:
If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings 'Do not take Enap if' and 'Warnings and precautions').

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

Enap with food, drink and alcohol
Alcohol can increase the effect of this medicine. Check with your doctor or pharmacist before drinking any alcohol.

Pregnancy 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 Enap before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enap. Enap 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.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Enap. In the case of an older baby your doctor should advise you on the benefits and risks of taking Enap whilst breast-feeding, compared to other treatments.

Driving and using machines
You may feel dizzy or sleepy while taking Enap. If this happens, do not drive or use any tools or machines.

Enap contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Enap contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Enap

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- It is important to continue taking Enap for as long as your doctor prescribes it.
- Do not take more tablets than prescribed.
- Enap can be taken with or without food. Most people take Enap with a drink of water.

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 maximum 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 maximum 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
Experience in the use of Enap 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 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 50 kg.

Enap is not recommended in newborn babies (first few weeks after birth) and in children with kidney problems.

If you take more Enap than you should
If you take more Enap than you should, talk to your doctor or go to a hospital straightaway.
Take the medicine pack with you. The following effects may happen: feeling of light-headedness or dizziness. This is due to a sudden or excessive drop in blood pressure.

If you forget to take Enap
• 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 Enap
Do not stop taking your medicine unless your doctor tells you to.

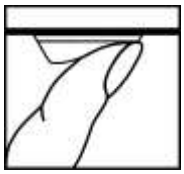
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

How to remove tablet from blister pocket

Step 1.

Slit the blister pocket from the printed side (with the fingernail) until it rips.

Step 2.



For easy removal of the tablet from the blister pocket, we recommend you press on the underside of the blister pocket.

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:

Stop taking Enap and talk to a doctor straightaway, if you notice any of the following:

- swelling of your face, lips, tongue or throat which may cause difficulty in breathing or swallowing
- swelling of your hands, feet or ankles
- if you develop a raised red skin rash (hives).

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happens, stop taking Enap and talk to your doctor straightaway.

When you start taking Enap you may feel faint or dizzy. If this happens, it will help to lie down. This is caused by your blood pressure lowering. It should improve as you continue to take the medicine. If you are worried, please talk to your doctor.

Other side effects include:

Very common: may affect more than 1 in 10 people

- feeling dizzy, weak or sick
- blurred vision
- cough.

Common: may affect up to 1 in 10 people

- low blood pressure, faintness or dizziness, especially when standing, changes in heart rhythm, fast heartbeat, angina or chest pain
- headache, fainting (syncope)
- change in sense of taste, shortness of breath
- diarrhoea or abdominal pain, rash
- tiredness (fatigue), depression
- allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing
- increased blood potassium level, increased levels of creatinine in your blood (both are usually detected by a test).

Uncommon: may affect up to 1 in 100 people

- sudden fall in blood pressure, especially when standing
- fast or uneven heart beats (palpitations)
- 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)
- anaemia (including aplastic and haemolytic)
- stroke (possibly due to very low blood pressure in high-risk patients)
- confusion, sleeplessness or sleepiness, nervousness
- feeling your skin prickling or being numb
- vertigo
- ringing in your ears (tinnitus)

• runny nose, sore throat or hoarseness
• asthma
• slow movement of food through your intestine, inflammation of your pancreas
• being sick (vomiting), indigestion, constipation, loss of appetite
• irritated stomach (gastric irritations), dry mouth, ulcer, impaired kidney function, kidney failure
• increased perspiration
• itching or nettle rash
• 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: may affect up to 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 disease
• strange dreams or sleep problems
• pulmonary infiltrates
• inflammation of your nose
• pneumonia
• inflammation of the cheeks, gums, tongue, lips, throat; mouth ulcers
• lower amount of urine produced
• erythema multiforme (redness or inflammation of the skin)
• 'Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin)
• liver problems such as lower liver function, liver failure, inflammation of your liver, jaundice (yellowing of the skin or eyes), higher levels of liver enzymes or bilirubin (measured in a blood test)
• enlargement of the mammary glands in males
• swollen glands in neck, armpit or groin.

Very rare: may affect up to 1 in 10,000 people
• swelling in your intestine (intestinal angioedema).

Not known: frequency cannot be estimated from the available data
• feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called syndrome of inappropriate anti-diuretic hormone secretion (SIADH).
• a complex group of side effects which may include some or all of the following: fever, inflammation of the lining of the lungs, inflammation of blood vessels, pain and inflammation of muscles or joints, abnormal blood tests, changes in blood values such as increased eosinophils and white blood cells. Rash sensitivity to light and other skin reactions may occur.

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. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Enap

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

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

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

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 Contents of the pack and other information

What Enap 5 mg Tablets contain:
- the active substance is enalapril maleate (5 mg).
- the other ingredients are sodium hydrogen carbonate, lactose monohydrate, maize starch, talc, hydroxypropylcellulose and magnesium stearate.

What Enap 10 mg Tablets contain:
- the active substance is enalapril maleate (10 mg).
- the other ingredients are sodium hydrogen carbonate, lactose monohydrate, maize starch, talc, magnesium stearate and ferric oxide red (E172).

What Enap 20 mg Tablets contain:
- the active substance is enalapril maleate (20 mg).
- the other ingredients are sodium hydrogen carbonate, lactose monohydrate, maize starch, talc, magnesium stearate, ferric oxide red (E172) and ferric oxide hydrate yellow (E172).

What Enap looks like and contents of the pack

Enap tablets are available in 3 strengths.
Enap 5 mg Tablets are oval, biconvex, white tablets, one side scored with markings of "EN 5". The tablets can be divided into equal halves.

Enap 5 mg Tablets are available in blister packs containing 30 or 50 tablets. Not all pack sizes may be marketed.

Enap 10 mg Tablets are oval, biconvex, red-brown tablets, one side scored with markings of "EN 10". The tablets can be divided into equal halves.

Enap 10 mg Tablets are available in blister packs containing 30 tablets.

Enap 20 mg Tablets are oval, biconvex, orange tablets, one side scored with markings of "EN 20". The tablets can be divided into equal halves.

Enap 20 mg Tablets are available in blister packs containing 30 tablets.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.
Lek Pharmaceuticals d.d.,Trimlini 2D,9220 Lendava, Slovenia.

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