

ENAP-H 10 mg/25 mg tablets

ENAP-HL 10 mg/12.5 mg tablets

ENAP-HL 20 20 mg/12.5 mg 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 Enap is and what it is used for
2. Before you take Enap
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4. Possible side effects
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1. WHAT ENAP IS AND WHAT IT IS USED FOR

Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12.5 mg are medicines for lowering blood pressure. ATC code: C09BA02.

Enalapril belongs to the group of angiotensin converting enzyme inhibitors, which widen the blood vessels and reduce blood pressure and increase blood flow and oxygen to the heart muscle and other organs.

Hydrochlorothiazide belongs to a group of medicines that increase the excretion of urine (diuretic). This medicine increases the excretion of urine and so reduces the blood pressure. The combination of enalapril and hydrochlorothiazide has stronger effect on lowering the blood pressure than the individual ingredients.

Your doctor prescribed Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 20 mg/12,5 mg because you have a disease called hypertension, or high blood pressure.

2. BEFORE YOU TAKE ENAP

Do not take Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12,5 mg:

- If you are allergic (hypersensitive) to enalapril maleate, hydrochlorothiazide or any of the ingredients of the medicine Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12.5 mg;
- If you are after taking similar medicines and already had a hypersensitivity reaction with itching, urticaria, shortness of breath or swelling of the face, hands, lips, mouth, throat or the eyelid (angioedema);
- If you have a hereditary angioedema or angioedema;
- If you are hypersensitive to sulfonamides;
- If you have severely impaired kidney or liver function;
- If you have narrowed arteries which supply the kidneys with blood;
- If you have problems urinating;
- If you are pregnant for more than three months (or in early pregnancy taking the medicine Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12,5 mg is not advisable – see section on pregnancy).

If you have diabetes or impaired kidney function and you are treated with blood pressure-lowering medicine containing aliskiren. Be careful with the Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12.5 mg:

- If you have low blood pressure and an imbalance of salts and fluids;
- If you are being treated for kidney disease;
- If you are being treated by hemodialysis;
- If you have recently had transplantation of kidney;
- If you are being treated for diabetes;
- If you are being treated for liver disease;
- If you are being treated for gout;
- If you are being treated for severe connective tissue disease (systemic lupus erythematosus);
- If you have damaged function of the heart valves or any other heart disease;
- If you are allergic to medicines from the group of sulfonamides;
- If you are taking water tablets;
- If you vomit or have diarrhea;
- If you know that you could have high levels of uric acid in the blood;
- If your doctor says that you have intolerance to some sugars;
- If you are taking lithium, which is used to treat some psychiatric disorders.
- If you are taking any of the medicines listed below, which are used to treat high blood pressure:
 - Angiotensin II receptor blocker (ARB) (also known as Sartana - eg, valsartan, telmisartan, irbesartan), especially if you have kidney problems associated with diabetes.
 - Aliskiren. "
 - Doctor may check your kidney function, blood pressure and the amount of electrolytes (eg, potassium) in the blood at regular intervals.

See also the information under the heading "do not take Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12.5 mg". Prior to a possible surgical procedure or anesthesia (also at the dentist) you have to tell that you are taking a combination of enalapril and hydrochlorothiazide.

When your doctor is planning

- treatment by hemodialysis;
- removal of cholesterol from the blood (Aphaeresis);
- the treatment of hypersensitivity reactions (desenzibilization) bees or wasps poison;
- tests on the work of the parathyroid gland (gland in the neck that control the value of calcium in the blood), the doctor who treated you have to say that you are taking a combination of enalapril and hydrochlorothiazide.

If you have Angina Pectoris and your condition during the taking of the combination of enalapril and hydrochlorothiazide gets worse, you must inform your doctor.

You must tell the doctor if you think you are pregnant (or if there is a possibility that you can get pregnant).

Medicine Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20mg/12,5 mg is not advisable in the early period of pregnancy, and you should not take it after the third month of pregnancy as it can cause serious harm to your baby (see section about pregnancy).

Do not give medicine to children because there is no data on the efficiency and tolerance in children.

Taking other medicines with Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12,5 mg:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. It primarily refers to:

- to other medicines for the treatment of high blood pressure;
- to potassium supplements, salt substitutes containing potassium or water tablets that save potassium (eg, spironolactone, amiodarone);
- to analgesic and anti-inflammatory drugs (NSAIDs, e.g., ibuprofen, diclofenac);
- to medicines for the treatment of depression (e.g., lithium, tricyclic antidepressants, antipsychotics),
- to medicines that increase the excretion of urine (diuretics);
- to medicines for reduction of cholesterol levels in the blood (eg. Cholestyramine resin, and colestipol);
- to medicines that suppress tumor growth (anti-cancer drugs, for example, cyclophosphamide, methotrexate);
- to medicines used to treat diseases such as rheumatism, arthritis, allergic conditions, asthma or certain blood diseases (corticosteroids);
- To medicines for the treatment of cardiac arrhythmias (procainamide, amiodarone or sotalol);
- To medicines for the treatment of heart failure (digitalis);
- to active medicinal substances contained in certain medications for cough and cold (sympathomimetics), noradrenaline and adrenaline, or which are applied in the treatment of low blood pressure, shock, heart failure, asthma or allergies; If this medicines are used together with Enap-H 10 mg / 25 mg, Enap-HL 10 mg / 12.5 mg or Enap-HL 20 mg / 12.5 mg they can cause high blood pressure;
- to medicines for diabetes treatment, such as insulin; if Enap-H 10 mg / 25 mg, Enap HL-10 mg / 12.5 mg or Enap HL-20 20 mg / 12.5 mg are used in combination with medicines to treat diabetes, sugar levels in your blood can be further lowered;
- Muscle relaxants (eg, tubocurarine, which is used in anesthesia);
- to preparations with gold, which are used in the treatment of arthritis (sodium aurothiomalate).

The doctor will perhaps have to change the dose and / or 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-H 10 mg / 25 mg, Enap-HL 10 mg / 12.5 mg and Enap-HL 20 20 mg / 12 5 mg "and" Warnings and precautions").

Food and drink

You can take the medicine during meals or after meals, with liquid. Do not drink alcoholic drinks during treatment because you may experience dizziness and vertigo, particularly when you get up. If that happens, you must stop drinking alcohol immediately.

Pregnancy and breastfeeding

Consult a doctor or pharmacist before taking any medicine.

Pregnancy

You must tell the doctor if you think you are pregnant (or if there is a possibility that you can get pregnant).

As a rule, he/she will advise you to stop taking Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 mg/12.5 mg, before you become pregnant or immediately when you find out that you are pregnant and recommend taking other medicine instead of Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 mg/12.5 mg.

Taking Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 mg/12.5 mg in the early period of pregnancy is not recommended.

You should not use it after the third month of pregnancy because it can seriously harm your child. Namely, the medicine-Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 mg/12.5 mg passes through the placenta and taking it after the third month of pregnancy can have possible harmful effects on the fetus and the newborn.

Breast feeding

Both enalapril and hydrochlorothiazide are excreted into breast milk.

Tell your doctor if you are breast-feeding or plan to start breastfeeding. During treatment with Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 mg/12.5 mg breast feeding of newborns (the first few weeks after birth), especially preterm infants is not recommended.

Because both active substances can seriously harm the infant, a doctor must introduce you to benefits and risks posed by taking Enap-H 10 mg / 25 mg, Enap-HL 10 mg / 12.5 mg or Enap-HL 20 mg / 12, 5 mg during lactation, with regard to the treatment with other medications.

Driving and using machines

Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 mg/12.5 mg may cause dizziness or fatigue, especially at the beginning of the treatment, and thus indirectly reduce the physical ability for driving or using machines.

Other warnings

Medicines-Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 mg/12.5 mg contain lactose. If your doctor told you that you have intolerance to some sugars, consult your doctor before using this medicine.

3. HOW TO TAKE ENAP

At the taking Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 mg/12.5 mg, exactly follow the doctor's instructions. If you are in doubt, consult your doctor.

The usual dose is one tablet once a day. If necessary, the dose can be increased to two tablets once daily.

If you are currently taking other diuretics (water tablets), before you start taking the drug, consult your doctor. Treatment with diuretics needs to complete two to three days before the start of treatment with Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 mg/12.5 mg.

Thiazide diuretics may not be suitable for patients with impaired renal function; they are unproductive in patients with creatinine clearance 0.5 ml/s or less (for example in moderate and severe damage of the liver function). In patients with creatinine clearance between 0.5 ml/s and 1.3 ml/s, it is recommended to start treatment with an appropriate dose of individual active substances.

Take the tablets whole, during meals or after meals, with liquid. Get used to taking the medicine regularly, in the morning, at the same time.

If you think that the effect of Enap-H 10 mg/25 mg or Enap-HL 10 mg/12.5mg, or Enap-HL 20 mg/12.5 mg too strong or too weak, you should consult a doctor.

If you take more Enap-H 10 mg/25 mg or Enap-HL 10 mg/12.5 mg, or Enap-HL 20 20 mg/12,5 mg than you should

The most common signs of overdosing are weakness, rapid heart rate, dizziness and fainting, which are a result of excessive lowering of blood pressure (hypotension). If you have mistakenly taken too many tablets, consult with your doctor as soon as possible.

If you forget to take Enap-H 10 mg/25 mg, or Enap-HL 10 mg/12.5 mg, or Enap-HL20 20 mg/12.5 mg

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Enap-H 10 mg/25 mg, or Enap-HL 10 mg/12.5 mg, or Enap-HL 2020 mg/12.5 mg

Discontinuation of treatment may eventually raise the blood pressure again, which increases the risk for complications caused by high blood pressure, above all on the heart, the brain and the kidneys.

If you have any further questions on the use of Enap-H 10 mg/25 mg, or Enap-HL 10 mg/12.5 mg, or Enap-HL 20 20 mg/12.5 mg, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines and Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL20 20 mg/12.5 mg can cause side effects.

Side effects are listed according to the following categories of frequency:

Very common: occurs in more than 1 in 10 patients who take the drug

Common: occurs in 1 to 10 in 100 patients

Uncommon: occurs in 1 to 10 in 1000 patients

Rare: occurs in 1 to 10 to 10000 patients

Very rare : occurs in less than 1 in 10000 patients

Unknown frequency: cannot be estimated on the basis of the available data.

You should immediately stop using the medicine and immediately consult a doctor if you experience itching, shortness of breath or wheezing, severe skin rash, or swelling of hands, mouth, throat, face or eyes. It is very important to immediately stop taking the medicine and see your doctor if there is a strong dizziness or light-headedness (especially at the beginning of treatment or after a dose increase or to get up).

Very common

- Blurred vision
- dizziness
- cough
- Nausea (nausea)
- Weakness (asthenia)

Common

- small concentration of potassium in the blood, increased values of cholesterol, triglycerides and uric acid in the blood
- headache, depression, fainting (syncope), change in taste
- lowering the pressure in a horizontal position and weakness, irregular heartbeat, chest pain (angina pectoris), fast heartbeat
- shortness of breath (Dyspnea)
- diarrhea, pain in the abdomen
- skin rash

- muscle spasms
- chest pain, fatigue
- increased concentration of potassium in the blood, increased creatinine in the serum

Uncommon

- anemia
- blushing, palpitations, heart stroke, possibly as a result of excessive lowering of blood pressure in patients with high risk of cardiovascular complications
- noise in the ears (Tinnitus)
- discharge from the nose (rhinorrhoea), sore throat and wheezing, asthma
- blockage of the bowel (ileus), inflammation of the pancreas (pancreatitis), vomiting, gastrointestinal disturbances (dyspepsia), accumulation of gas in the intestine (flatulence), constipation, loss of appetite (anorexia), irritable, dry mouth, stomach ulcer
- renal, kidney failure, in serum proteins (proteinuria)
- itching, sweating, hair loss
- pain in the joints (arthralgia)
- the feeling of trembling (due to the low concentration of sugar in the blood), a small concentration of magnesium, gout
- impotence
- unpleasant feeling, elevated body temperature
- distractions, reducing libido, insomnia, drowsiness and nervousness, dizziness, tingling or stinging sensation in the hands or feet (paraesthesia)
- increased the concentration of urea in serum, reduced the concentration of sodium in the blood

Rare

- changes in the blood (neutropenia, hypohemoglobinemia, reduced hematocrit, thrombocytopenia, leucopenia)
- increased the concentration of glucose in the blood
- strange dreams, sleep disorders, the numbness has worn off (paresis)
- swollen glands, autoimmune disease, poor blood supply to the fingers and toes, which causes the redness and pain (Raynaud's syndrome)
- fluid in the lungs, discharge from the nose or inflammation of the nasal Mucosa, Eosinophilic Pneumonitis (characters can be cough, elevated body temperature and difficult breathing)
- swelling or ulcers in the mouth, infection or painful and swollen tongue
- liver misfire or hepatitis, which can cause yellowing of the skin (jaundice)
- reddish colored skin, skin rash with blisters and inflammation of the skin, especially on the hands and feet, in the mouth or around the mouth, and with a high temperature (Stevens-Johnson Syndrome), peeling of skin
- difficulties with kidney problems such as pain in the lower back and decreased urine excretion
- breast enlargement in men
- increased activity of liver enzymes or increased bilirubin in the blood

Very rare

- swelling of the intestinal lining; signs may include abdominal pain, nausea and vomiting
- increased the concentration of calcium in the blood

Unknown frequency

Not known

- Hyponatremia (which causes the syndrome of inappropriate antidiuretic hormone)

The complex symptoms were:

fever, serositis, vasculitis, myalgia / myositis, arthralgia / arthritis, increased titers of antinuclear antibodies (ANA), accelerated erythrocyte sedimentation rate, eosinophilia and leukocytosis.

If you notice any side effects please tell your doctor or pharmacist.

5. HOW TO STORE ENAP

Keep out of the reach and sight of children.

Store in the original packaging to ensure protection from moisture.

Keep at temperature up to 30 ° C in the original packaging to ensure protection from moisture.

Medicines-Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg and Enap-HL 20 20 mg/12.5 mg must not be used after the expiry date that is specified on the packaging. Expiration date refers to the last day of that month.

The shelf life of the medicinal product Enap-HL 10 mg/12.5 mg is 3 years from the date of production.

The shelf life of the medicinal product Enap-HL 20 20 mg/12.5 mg is 5 years from the date of production.

The shelf life of the medicinal product-Enap-H 10 mg/25 mg tablets is 5 years from the date of production.

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.

6. FURTHER INFORMATION

What Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 20 mg/12.5 mg contains?

Active substances are maleate and hydrochlorothiazide.

Each Enap-H 10 mg/25 mg tablet contains 10 mg of enalapril maleate, which corresponds to 7.64 mg of enalapril and 25 mg of hydrochlorothiazide.

Each Enap-HL 10 mg/12.5 mg tablet contains 10 mg of enalapril maleate, which corresponds to 7.64 mg of enalapril and 12.5 mg of hydrochlorothiazide.

Each Enap-HL 20 20 mg/12.5 mg tablet contains 20 mg of enalapril maleate, which corresponds to 15.29 mg of enalapril and 12.5 mg of hydrochlorothiazide.

- The other ingredients Enap-H 10 mg/25 mg tablets are lactose monohydrate, quinoly yellow colors (E104), maize starch, pregelatinized starch, talc, sodium hydrogen carbonate, magnesium stearate.
- The other ingredients Enap-HL 10 mg/12.5 mg tablets are lactose monohydrate, maize starch, pregelatinized starch, talc, sodium hydrogen carbonate, magnesium stearate.
- The other ingredients Enap-HL 20 20 mg/12.5 mg tablets are lactose monohydrate, corn starch, sodium bicarbonate, pregelatinized starch, talc, magnesium stearate.

How does-Enap-H 10 mg/25 mg, Enap-HL 10 mg/12.5 mg, or Enap-HL 20 20 mg/12.5 mg look like and contents of the pack?

Enap-H 10 mg/25 mg tablets are yellow in color, round, flat, with a division line on one side. Division line is not intended for breaking the tablets.

Enap-HL 10 mg/12.5 mg tablets and Enap-HL 20 20 mg/12.5 mg tablets are white, round, flat, with a division line on one side. Division line is not intended for breaking the tablets.

Enap-H 10 mg/25 mg tablets and Enap-HL 10 mg/12.5 mg tablets are available in carton boxes of 20 (2 x 10) or 30 (3 x 10) tablets in blisters.

Enap-HL 20 20 mg/12.5 mg tablets are available in carton boxes of 20 (2 x 10), 30 (3x 10), tablets in blisters.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Krka, tovarna zdravil, d.d.

Šmarješka cesta 6, Novo Mesto, the Republic of Slovenia

Manufacturer of the medicinal product

Krka, tovarna zdravil, d.d.

Šmarješka cesta 6, Novo Mesto, the Republic of Slovenia