

Package leaflet: Information for the user

ENEAS 10 mg/20 mg tablets

Enalapril maleate/Nitrendipine

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. Do not pass it on to others. It may harm them, even if their symptoms 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 Eneas is and what it is used for
2. What you need to know before you take Eneas
3. How to take Eneas
4. Possible side effects
5. How to store Eneas
6. Content of the pack and other information

1. What Eneas is and what it is used for

Enalapril maleate belongs to a group of medicinal products known as angiotensin converting enzyme inhibitors (ACE inhibitors). Nitrendipine belongs to a group of medicinal products known as calcium channel antagonists.

It is indicated in the treatment of high blood pressure in patients who cannot be adequately controlled on enalapril or nitrendipine alone.

2. What you need to know before you take Eneas

Do not take Eneas

- If you are allergic (hypersensitive) to enalapril maleate, nitrendipine or any of the other ingredients of Eneas (see composition on section 6).
- If you have suffered allergic reactions to similar medicinal products.
- If you are more than 3 months pregnant. (It is also better to avoid Eneas in early pregnancy – see pregnancy and breast feeding section).
- If you have cardiovascular shock, cardiac insufficiency and you have been diagnosed with angina pectoris, myocardial infarct or cerebral infarct in the previous days.
- If you suffer serious renal impairment or are on haemodialysis treatment.
- If you suffer from serious liver failure.
- If you have diseases caused by narrow heart valves.

- If you have narrow renal arteries.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- In case of children and adolescents.

Warning and precautions

Talk to your doctor before taking Eneas.

- If you have swollen face, lips, tongue and/or larynx, interrupt the treatment and see your doctor immediately.
- If you suffer from a disease of the connective tissue affecting the vascular system (collagen vascular disease), if you receive a therapy which reduces the defence system of the body (immuno suppressant-therapy) and/or receive a treatment with allopurinol or procainamide, especially if you have impaired kidney function. Your doctor will regularly monitor your white blood cell count.
- If you have kidney disease your doctor may have certain tests carried out during treatment with this medicinal product.
- If you suffer from a mild to moderate limitation of your liver function.
- You must tell your doctor if you think you are (or might become) pregnant. ENEAS 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 and breast feeding section).
- If you have fever or infection during treatment, your doctor should be informed as soon as possible.
- If you have heart problems.
- If you receive a treatment due to a severe disorder of metabolism (LDL apheresis) or due to an allergic responsiveness to insect stings (immune therapy), because life-threatening hypersensitivity reactions might occur. Your doctor will temporarily replace ENEAS by another medicinal product for high blood pressure.
- If you have side effects at the beginning of treatment.
- If you have loss of fluids due to the use of diuretic medicinal products, diarrhoea or vomiting; from low salt diet, or other reasons, as you may have a sensation of dizziness on changing position suddenly.
- If you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), 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 Eneas”.

See your doctor, even if any of the aforementioned circumstances occurred once.

During the treatment with ENEAS your doctor will regularly perform medical test. Keep the appointments for checkups of your doctor.

Other medicines and Eneas

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 Eneas” and “Warnings and precautions”).

Eneas may increase the effect of other medicinal products for the treatment of high blood pressure.

- **Do not take** Eneas with
 - potassium sparing diuretics (a type of diuretics that may increase potassium levels).
 - potassium supplements (salt substitutes containing potassium).
 - or other drugs that can rise blood potassium levels.

- **Be particularly careful** if you are being treated with any of the following medicines:
 - Lithium (a medicine used to treat some types of psychiatric illness).
 - muscular relaxants (a type of medicines used to alleviate symptoms such as muscle spasms).
 - non-steroidal antiinflammatories (a type of medicines used to relieve pain, swelling and other symptoms of inflammation).
 - oral antidiabetics
 - baclofen (an medicine used to treat spasticity).
 - antipsychotics (a type of medicines to treat some type of psychiatric disorders).
 - antidepressants
 - allopurinol (a medicine used to treat chronic gout).
 - cytostatics (a type of medicines used to treat malignant disease, like cancer)
 - Immunosuppressants (a type of medicines used to cause the suppression of the immune system (used to prevent the body from rejecting a transplanted organ).
 - systemic glucocorticoids
 - procainamide (a medicine used to treat cardiac arrhythmias).
 - amifostine (a medicine used during the treatment of some type of malignant diseases, like cancer)
 - cimetidine (a medicine used to treat duodenal and gastric ulcers).
 - ranitidine (a medicine used to treat duodenal and gastric ulcers).
 - digoxin (a medicine used to treat congestive heart failure).
 - anticonvulsants
 - rifampicin (an antibiotic medicine).
 - and medicines for the treatment of infections caused by fungi.

Eneas with food and drink

Eneas can be taken with meals.
Do not take grapefruit juice at the same time as Eneas.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Eneas before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Eneas. Eneas 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.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Eneas is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is new born, or was born prematurely.

Fertility

In isolated cases of in vitro fertilisation, nitrendipine, one of active substance of Eneas, have been associated with an alteration of sperm function. In men, there are cases of repeat paternity failure of in vitro fertilization, and when no other explanation is available, Eneas must be regarded as a possible reason.

Driving and using machines

This medicine may affect your ability to drive or use machines at the beginning of treatment, whereby caution is recommended in this phase.

Eneas contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take Eneas

Always take Eneas exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Remember to take your medicine.

Your doctor will tell you how long your treatment with Eneas will last. Do not interrupt the treatment before that.

The recommended dose is 1 tablet a day, taken with a little water. Tablets must be swallowed whole, not broken up or chewed.

If you take more Eneas than you should

If you have taken more Eneas than you should, see your doctor or pharmacist immediately. In this case you may have an excessive fall in blood pressure.

If you forget to take Eneas

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

If you stop taking Eneas

Do not stop treatment unless your doctor tells you to.

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.

- **Usual adverse reactions (common, 1-10%):** headache, facial redness, cough and swollen legs.
- **Uncommon adverse reactions (0,1-1%):** dizziness, tachycardia, erythematous rash, nausea, dyspepsia and hypotension.
- **Very rare (<0.01%):** Isolated cases of asthenia, hypotermia, palpitation, peripheral ischaemia, blood in urine, pharyngitis, tracheitis, difficulty breathing, abdomen enlarged, alteration of hepatic analytical tests, alteration of blood potassium levels, somnolence, tingling sensation, tremor and cramps.

The following adverse reactions might occur a well, as they have been associated with the use of either drug (Enalapril or Nitrendipin) in monotherapy:

General:

Occasionally: flu symptoms.

Cardiovascular system:

Occasionally: heart failure, high blood pressure, unconsciousness, arrhythmias, vasodilatation.

Rarely (including isolated cases): angina pectoris, chest pain, myocardial infarction, vascular occlusion due to blood clot, pulmonary infarction.

Kidney:

Occasionally: renal impairment.

Rarely (including isolated cases): oliguria (less urination than normal), proteinuria (increased protein in urine), urinary urge, increased urinary output, flank pain.

Respiratory tract:

Occasionally: sore throat, Hoarseness, bronchitis.

Rarely (including isolated cases): bronchospasm/asthma, pulmonary infiltrates, pneumonia, paranasal sinuses (inflammation of paranasal sinuses), common cold, sudden swelling of the pharynx with fatal respiratory constriction in individual cases, with a greater incidence in black patients.

Gastrointestinal tract / liver:

Occasionally: upper abdominal pain, diarrhoea.

Rarely (including isolated cases): constipation, loss of appetite, hepatitis, liver function disorders, pancreatitis, ileus (a syndrome beginning with cholestatic jaundice (yellow staining of the skin and mucosa due to the obstruction of the flow of bile) and progression to hepatic necrosis with fatal outcome in some cases).

Skin, vessels:

Occasionally: allergic skin reactions.

Rarely (including isolated cases): hives, pruritus, severe skin reaction, psoriasis-like rash, photosensitivity, diaphoresis (excess sweating), hair loss, onycholysis (finger nail removal), skin changes may be connected with fever, sudden swelling of the face, mouth, and/or extremities, blood vessel inflammation, inflammation of the skin.

Nervous system:

Rarely (including isolated cases): drowsiness, depression, sleep disorders, impotence, disturbance of balance, muscle cramps, nervousness, confusion.

Endocrine:

Rarely (including isolated cases): gynecomastia (excessive development of the breasts in males).

Sensory organs:

Rarely (including isolated cases): changes in taste reception or transient loss of taste, anosmia (loss of the sense of smell), tinnitus (ear buzzing), dry eyes, tearing.

Musculo-skeletal:

Rarely (including isolated cases): myalgia (muscle pain), arthralgia (joint pain),

Laboratory parameters:

Occasionally: Changes in the blood count, changed uric quality.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Eneas

Store below 30°C.

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

Do not use ENEAS after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that 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.

6. Contents of the pack and other information

What Eneas contains

- The active substances are enalapril maleate and nitrendipine. Each tablet contains 10 mg of enalapril maleate and 20 mg of nitrendipine.
- The other ingredients are sodium hydrogen carbonate, lactose monohydrate, cellulose microcrystalline, maize starch, povidone, sodium laurilsulfate, magnesium stearate.

What Eneas looks like and contents of the pack

Tablets are oblong biconvex yellow tablets, with the engraving “E/N” on one side. Eneas is presented in packs of 20, 30, 50, 60, 100, 300 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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