

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

Enalapril Unicorn 5 (Tablets)

Enalapril Unicorn 10 (Tablets)

Enalapril Unicorn 20 (Tablets)

Enalapril maleate

Enalapril Unicorn 5: Contains sugar: Lactose 40 mg per tablet

Enalapril Unicorn 5: Contains sugar: Lactose 80 mg per tablet

Enalapril Unicorn 5 : Contains sugar: Lactose 80 mg per tablet

Read this entire leaflet carefully before you start taking Enalapril Unicorn

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor pharmacist, nurse or other health care provider.
- Enalapril Unicorn has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ENALAPRIL UNICORN is and what it is used for
2. What you need to know before you take ENALAPRIL UNICORN
3. How to take ENALAPRIL UNICORN

4. Possible side effects
5. How to store ENALAPRIL UNICORN
6. Contents of the pack and other information

1. What ENALAPRIL UNICORN is and what it is used for

Enalapril belongs to a class of medicines called ACE inhibitors. Enalapril Unicorn is used to treat high blood pressure and to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

2. What you need to know before you take ENALAPRIL UNICORN

Do not take ENALAPRIL UNICORN:

- if you are hypersensitive (allergic) to enalapril, or to any of the other ingredients of Enalapril Unicorn TABLETS (listed in section 6).
- if you have previously been treated with a medication in the same group of medicines as Enalapril Unicorn (ACE inhibitors) or with a medication in the group of medicines known as angiotensin receptor blockers and have had allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing.
- if 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.
- if you have severe kidney dysfunction.
- if you have kidney problems, where the blood supply to your kidney is reduced (renal artery stenosis).
- if you are also taking potassium sparing diuretics such as spironolactone, triamterene, amiloride.

- if you are also receiving lithium therapy: Administration together with ENALAPRIL UNICORN may lead to toxic blood concentrations of lithium.
- if you have a hereditary condition called porphyria.
- if you are pregnant or breast-feeding (see Pregnancy and Breast-feeding).
- if you are taking aliskiren containing products
- if you are taking antibiotics belonging to fluoroquinolone family (eg. Ciprofloxacin, levofloxacin etc.)

Warnings and precautions

Take special care with Enalapril Unicorn:

Should you become pregnant while receiving Enalapril Unicorn, Enalapril Unicorn must be stopped immediately. Consult your doctor if you are contemplating pregnancy.

- 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
- if you are at risk of low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- if you have been very sick (excessive vomiting) or had bad diarrhoea recently.
- if you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents (such as spironolactone, triamterene, amiloride), or potassium-containing salt substitutes.
- if you have any heart problem or heart disease.

- if you have any other kidney problems (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 enalapril or monitor your blood level of potassium.
- if you are an elderly person (over 65 years of age).
- if you are on dialysis.
- if you have liver problems.
- if 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 cells (anaemia).
- if 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 such as Enalapril Unicorn. Signs of swelling of the face or arms and legs or difficulty in swallowing or breathing require immediate medical attention because of the risk of angioedema.
- if you have lupus, rheumatoid arthritis, scleroderma, or if you are on therapy that suppresses your immune system.
- if you are taking the medicines allopurinol for gout or any combinations of these.
- if 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.
- The safety and efficacy of Enalapril Unicorn in children have not been established.

Your doctor will conduct some blood tests before and during the treatment to examine if your kidneys are working properly.

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

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 Enalapril Unicorn:

- Any surgery or receive anaesthetics (even at the dentist).
- A treatment to remove cholesterol from your blood called “LDL apheresis”.
- A desensitization 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 ENALAPRIL UNICORN

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Care is needed if you are taking following medicines along with Enalapril Unicorn:

- Angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan) or aliskiren.
- Medicines containing potassium (including dietary salt supplements).
- 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 “antipsychotics”.
- Other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics), such as furosemide, hydrochlorothiazide, spironolactone, triamterene or amiloride.
- Medicines used for arthritis or gout (allopurinol, cytostatic or immune-suppressive agents, systemic corticosteroids).
- Gold therapy such as sodium aurothiomalate, which can lead to flushing of your face, feeling sick (nausea or vomiting) and low blood pressure.

- Ciclosporin (medicine used for organ transplant, arthritis or psoriasis).
- Non-steroidal anti-inflammatory medicines (NSAIDs), e.g. ibuprofen, including COX-2-inhibitors, e.g. celecoxib (medicines that reduce inflammation, and can be used to help relieve pain).
- Certain cough and cold medicines and cold medicines and weight reducing medicines which contain an ingredient called a “sympathomimetic agent”.
- Alcohol
- Fluoroquinolones eg. Ciprofloxacin, levofloxacin [see also information under the headings “Do not take Enalapril Unicorn and Take special care with Enalapril Unicorn”).

Enalapril Unicorn with food and drink

Enalapril Unicorn can be taken before, during or after a meal.

Pregnancy and breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You must not take Enalapril Unicorn if you are pregnant or breast-feeding. If you are pregnant or become pregnant while taking Enalapril Unicorn, stop taking Enalapril Unicorn and talk to your doctor as soon as possible. If you are a woman of childbearing age, ensure that you take adequate contraceptive measures.

If you are pregnant or breast-feeding your baby, please consult your health care provider for advice before taking Enalapril Unicorn.

Driving and using machinery

Caution is necessary when driving or performing tasks requiring alertness, as some people may feel dizzy or sleepy during treatment with Enalapril Unicorn. Do not drive or operate any tools or machines until you know how Enalapril Unicorn affects you because your concentration may be affected.

Enalapril Unicorn contains lactose

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

Enalapril Unicorn contains sodium

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

3. HOW TO TAKE ENALAPRIL UNICORN

Do not share medicines prescribed for you with any other person.

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

Since food does not interfere with the absorption of Enalapril Unicorn, the dose may be administered before, during or after meals.

Hypertension: The usual starting dose is 10 to 20 mg once daily. The maintenance dose is usually 20 mg once daily. Your doctor will adjust your dose according to your specific needs.

Take your tablet(s) with a glass of water, preferably at the same time each day, in the morning.

If you are an elderly patient (over 65 years of age) or if you have kidney problems, your doctor will start your treatment with Enalapril Unicorn on a lower dose of 2,5 mg once daily and adjust your dose according to your response and blood pressure.

Heart failure: The usual starting dose of Enalapril Unicorn is 2,5 mg once daily *under medical supervision*, and your doctor will adjust your dose according to your response. If you have severe heart failure, your treatment with Enalapril Unicorn will be started while you are in hospital, where you can be closely monitored by your doctor.

To help yourself remember to take Enalapril Unicorn, try to take it at the same time each day. Take your tablets as directed and for as long as directed; do not stop them, even if you feel better, as the symptoms may return.

If you have the impression that the effect of Enalapril Unicorn is too strong or too weak, talk to your doctor or pharmacist.

If you take more Enalapril Unicorn than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take Enalapril Unicorn at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. **Do not take a double dose** to make up for forgotten individual doses.

Effects when treatment with Enalapril Unicorn is stopped:

Take **Enalapril Unicorn** for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. POSSIBLE SIDE-EFFECTS

Enalapril Unicorn can have side-effects.

Not all side-effects reported for Enalapril Unicorn are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Enalapril Unicorn, please consult your healthcare provider for advice.

If any of the following happen, stop taking Enalapril Unicorn and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the arms, legs, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing,
- rash or itching,

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to Enalapril Unicorn. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side-effects:

- Cough, difficulty in breathing.
- Headache, depression.
- Blurred vision.
- Feeling dizzy, lightheadedness, fainting.
- Chest pain, irregular heartbeat, fast heart beat.
- Feeling sick (nausea), diarrhoea, stomach pain, disturbances in taste.

- Skin rash.
- Unusual tiredness or weakness.

Less frequent side-effects:

- Vomiting, indigestion, constipation, loss of appetite, dry mouth, blockage in the bowel (constipation), stomach ulcer, irritated stomach; swollen, red, sore tongue; mouth ulcers and cold sores, dark stools, swelling of your intestine.
- Muscle cramps.
- Asthma, runny nose, sore throat or hoarseness.
- Kidney or urination problems, infection in urinary passage, kidney failure.
- Sudden fall in blood pressure, palpitations.
- Heart attack or stroke (possibly due to very low blood pressure in high-risk patients).
- Changes in blood values such as a lower number of white and red blood cells, lower hemoglobin, lower number of blood platelets.
- 'Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow.
- Hepatitis or jaundice (yellow eyes or skin), liver failure, higher levels of liver enzymes or bilirubin (measured in a blood test).
- Inflammation of the cheeks, gums, tongue, lips, throat.
- Confusion, sleepiness, trouble in sleeping, nervousness, sleep disorders, strange dreams.
- Numbness or weakness of the arms and legs.
- Impotence, enlargement of the mammary glands in males.
- Flushing, generally feeling unwell (malaise), high temperature (fever), ringing in the ears, loss of smell, swollen runny eyes, dry eyes, tearing, flank pain.
- Excessive sweating, itching, hives, hair loss.

- A rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals and other skin related problems.
- Low level of blood sugar or sodium, high level of creatinine, potassium, urea in blood (all measured in a blood test).

If you notice any side-effect not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of Enalapril Unicorn.

5. How to store Enalapril Unicorn

- Store at or below 25 °C, protected from moisture.
- KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What Enalapril Unicorn contains

The active substance is Enalapril maleate 5 mg, 10 mg or 20 mg per tablet.

The other ingredients:

Enalapril Unicorn 5: Colloidal anhydrous silica, croscarmellose sodium (AC-DI-SOL), lactose (Pharmatose DCL 11), maleic acid, microcrystalline cellulose (PH112), zinc stearate.

Enalapril Unicorn 10: Colloidal anhydrous silica, croscarmellose sodium (AC-DI-SOL), ferric oxide red (CI No. 77491), lactose (Pharmatose DCL 11), maleic acid, microcrystalline cellulose (PH112), zinc stearate.

Enalapril Unicorn 20: Colloidal anhydrous silica, croscarmellose sodium (AC-DI-SOL), ferric oxide red (CI No. 77491), ferric oxide yellow (CI No. 77492), lactose (Pharmatose DCL 11), maleic acid, microcrystalline cellulose (PH112), zinc stearate.

What Enalapril Unicorn looks like and contents of the pack

Enalapril Unicorn 5

White to off-white round, biconvex uncoated tablets debossed with 'ENP005' and a break line on one side and 'R' on the other.

Enalapril Unicorn 10

Pink, round biconvex uncoated tablets debossed with 'ENP010' on one side and 'R' on the other.

Enalapril Unicorn 20

Peach coloured round, biconvex, uncoated tablets debossed with 'ENP020' on one side and 'R' on the other.

Contents of the pack:

Enalapril Unicorn 5: Carton containing 4 blister strips of 7 tablets in each blister.

Enalapril Unicorn 10: Carton containing 4 blister strips of 7 tablets in each blister.

Enalapril Unicorn 20: Carton containing 4 blister strips of 7 tablets in each blister.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd.

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