

PACKAGE LEAFLET: INFORMATION FOR THE USER

Eprosartan Niche 300 mg Film-coated Tablets

Eprosartan Niche 400 mg Film-coated Tablets

Eprosartan Niche 600 mg Film-coated Tablets

Eprosartan

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 Eprosartan Niche is and what it is used for
2. What you need to know before you take Eprosartan Niche
3. How to take Eprosartan Niche
4. Possible side effects
5. How to store Eprosartan Niche
6. Contents of the pack and other information

1. What Eprosartan Niche is and what it is used for

Eprosartan Niche contains the active substance eprosartan.

Eprosartan belongs to a group of medicines called ‘angiotensin II receptor antagonists’. It blocks the action of a substance in your body called ‘angiotensin II’. This substance causes your blood vessels to narrow. This makes it more difficult for the blood to flow through the vessels and so your blood pressure increases. By blocking this substance, the vessels relax and your blood pressure decreases.

Eprosartan is used to treat high blood pressure (hypertension).

2. What you need to know before you take Eprosartan Niche

Do not take Eprosartan Niche:

- if you are allergic to eprosartan or any of the other ingredients of this medicine (listed in Section 6)
- if you have **severe** liver disease
- if you have **severe** problems with the blood flow in your kidneys or serious restriction to blood flow in a single functioning kidney
- if you are more than 3 months pregnant (it is also better to avoid eprosartan in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Eprosartan Niche.

Check with your doctor or pharmacist before taking this medicine if:

- you have any other liver problems

- you have any other kidney problems. Your doctor will check how well your kidneys are working before you start your treatment and at intervals during your treatment. Your doctor will also check the potassium, 'creatinine' and 'uric acid' levels in your blood
 - you have a heart problem such as coronary heart disease, heart failure, a narrowing of your blood vessels or heart valves, or a problem with your heart muscle
 - you produce too much of a hormone called 'aldosterone'
 - you are on a low-salt diet, taking 'water tablets' or are being sick or have diarrhoea. This is because they may cause your blood volume or the sodium level in your blood to decrease. These should be corrected before starting treatment with Eprosartan Niche
 - you know you have raised potassium levels in your blood
 - you think you are (or might become) pregnant. Eprosartan Niche 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 taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), 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 Eprosartan Niche.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Eprosartan Niche.

Children and adolescents

Children and adolescents under 18 years should not take eprosartan.

Other medicines and Eprosartan Niche

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

In particular, tell your doctor or pharmacist if you are taking the following:

- lithium – for mood problems. Your doctor must monitor the lithium level in your blood because Eprosartan may increase the level.
- Medicines for pain and inflammation such as ibuprofen, diclofenac, celecoxib, etoricoxib or lumiracoxib (non-steroidal anti-inflammatory medicines).

The following medicines may increase the effect of Eprosartan Niche:

- medicines that lower your blood pressure.

The following medicines may decrease the effect of Eprosartan Niche:

- indometacin – for pain, stiffness, swelling and lowering a high temperature.

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Eprosartan Niche.

If you are taking any of the following medicines your doctor may carry out blood tests:

- medicines containing potassium or potassium-sparing medicines
- medicines that increase potassium levels such as 'heparin' and 'ACE inhibitors'.

Talk to your doctor or pharmacist before taking Eprosartan Niche. Depending on the outcome of your blood tests, your doctor may decide to change your treatment with these medicines or Eprosartan Niche.

Your doctor may need to change your dose and / or take other precautions:

- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take Eprosartan Niche' and 'Warnings and precautions')

Eprosartan Niche with food and drink

- You can take the tablets with or without food.
- Speak to your doctor before taking Eprosartan Niche if you are on a low-salt diet. Not having enough salt may cause your blood volume or the sodium level in your blood to get lower.

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 Eprosartan Niche before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Eprosartan Niche.
- Eprosartan Niche is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant. 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.
- Eprosartan Niche is not recommended for mothers who are breast-feeding. Your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

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.

Driving and using machines

Eprosartan Niche is unlikely to affect your ability to drive or use tools and machines. However, you may feel sleepy or dizzy while taking Eprosartan Niche. If this happens, do not drive or use any tools or machines and talk to your doctor.

Eprosartan Niche contains lactose (a type of sugar)

If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take Eprosartan Niche

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

Adults

The recommended dose is 600 mg eprosartan once daily.

Use in children and adolescents

Eprosartan Niche should not be given to children and adolescents aged under 18 years.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablet whole with plenty of fluid, such as a glass of water
- Do not crush or chew the tablets
- Take the tablets in the morning at around the same time each day

If you take more Eprosartan Niche than you should

If you take more Eprosartan Niche than you should or someone accidentally takes some, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects can happen:

- feeling light-headed and dizzy due to a fall in your blood pressure (hypotension)
- feeling sick (nausea)
- feeling sleepy

If you forget to take Eprosartan Niche

- If you forget a dose, take it as soon as you remember it.
- If you forget to take a dose and it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Eprosartan Niche

Do not stop taking Eprosartan Niche without talking to your doctor first.

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:

Allergic reactions (may affect up to 1 in 100 people)

If you have an allergic reaction, stop taking and see a doctor straight away. The signs may include:

- skin reactions such as a rash or hives with swelling (urticaria)
- swelling of the lips, face, throat or tongue
- shortness of breath
- swelling of your face, swelling of skin and mucous membrane (angiodema)

Other possible side effects of Eprosartan Niche include:**Very common:** may affect more than 1 in 10 people

- headache

Common: may affect up to 1 in 10 people

- viral infection
- raised fat (triglyceride) levels in the blood
- feeling dizzy, feeling unusually tired
- feeling depressed
- chest pain, palpitations (missed heart beats)
- back or joint pain
- urinary tract infection
- rash, itching and hives
- feeling sick, being sick, diarrhoea, stomach pain, indigestion
- feeling weak (asthenia)
- stuffy nose (rhinitis), sore or hoarse throat, breathlessness, cough, chest infection
- general pain

Uncommon: may affect up to 1 in 100 people

- low blood pressure. You may feel light-headed or dizzy.
- too high potassium levels in the blood
- swelling under the skin
- allergic reaction

Rare: may affect up to 1 in 1000 people

- anaemia
- increased urea levels in the blood

Not known: frequency cannot be estimated from the available data

- loss of muscle tone and strength
- dizziness on standing up
- swelling of the face
- kidney problems, including kidney failure

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Eprosartan Niche

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 carton and blister foil after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Eprosartan Niche contains

The active substance is eprosartan (as mesilate). Each tablet contains either 300 mg, 400 mg or 600 mg of eprosartan.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, silica colloidal anhydrous, povidone, polysorbate 80, crospovidone, magnesium stearate.

Film-coating: hypromellose, hydroxypropylcellulose (E463), titanium dioxide (E171), macrogol 400. The film-coating for the 400 mg tablets also contains yellow and red iron oxides (E172).

What Eprosartan Niche looks like and contents of the pack

The 300 mg tablets are white, ovaloid shaped, biconvex film-coated tablets. The 400 mg tablets are peach-coloured, oval shaped, biconvex film-coated tablets. The 600 mg tablets are white, capsule shaped, biconvex film-coated tablets.

Eprosartan Niche tablets are available in aluminium blister packs containing 4, 7, 14, 28, 50, 56, 98 and 280 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Niche Generics Ltd., 1 The Cam Centre, Wilbury Way, Hitchin, SG4 0TW, United Kingdom

Manufacturer:

Niche Generics Limited, Unit 5, 151 Baldoyle Industrial Estate, Dublin 13, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland, UK	Eprosartan Niche 300 mg film-coated tablets Eprosartan Niche 400 mg film-coated tablets Eprosartan Niche 600 mg film-coated tablets
Germany	Eprosartan Unichem 600 mg filmtabletten
The Netherlands	Eprosartan Unichem 400 mg filmomhulde tabletten Eprosartan Unichem 600 mg filmomhulde tabletten

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