

Package leaflet: Information for the patient

Renofrin 375 mg, tabletten met verlengde afgifte
Renofrin 500 mg, tabletten met verlengde afgifte
Renofrin 750 mg, tabletten met verlengde afgifte
ranolazine

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Renofrin is and what is used for

Renofrin is a medicine used in combination with other medicines to treat angina pectoris, which is a chest pain or discomfort that you feel anywhere along the upper part of your body between your neck and upper abdomen, often brought on by exercise or too much activity.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Renofrin

Do not take Renofrin

- if you are allergic to ranolazine or any of the other ingredients of this medicine listed in section 6 of this leaflet.
- if you have severe kidney problems.
- if you have moderate or severe liver problems.
- if you are using certain medicines to treat bacterial infections (clarithromycin, telithromycin), fungal infections (itraconazole, ketoconazole, voriconazol, posaconazol), HIV infection (protease inhibitors), depression (nefazodone) or heart rhythm disorders (e.g. quinidine, dofetilide or sotalol).

Warning and precautions

Talk to your doctor before taking Renofrin:

- if you have mild or moderate kidney problems.
- if you have mild liver problems.
- if you have ever had an abnormal electrocardiogram (ECG).
- if you are elderly.
- if you have low weight (60 kg or less).
- if you have heart failure.

Your doctor may decide to give you a lower dose or take other precautions if any of these apply to you.

Other medicines and Renofrin

Do not use the following medicines if you take Renofrin:

- certain medicines to treat bacterial infections (clarithromycin, telithromycin), fungal infections (itraconazole, ketoconazole, voriconazole, posaconazole), HIV infection (protease inhibitors), depression (nefazodone) or heart rhythm disorders (e.g. quinidine, dofetilide or sotalol).

Tell your doctor or pharmacist before you take Renofrin if you use:

- certain medicines to treat a bacterial infection (erythromycin) or a fungal infection (fluconazole), a medicine used to prevent rejection of a transplanted organ (ciclosporin) or if you are taking some heart tablets such as diltiazem or verapamil. These medicines may cause an increase in the number of side effects, such as dizziness, nausea or vomiting, which are possible side effects of Renofrin (see section 4). Your doctor may decide to give you a lower dose.
- medicines to treat epilepsy or another neurologic disorder (e.g. phenytoin, carbamazepine or phenobarbital); are taking rifampicin for an infection (e.g. tuberculosis); or are taking the herbal remedy St. John's Wort, as these medicines may cause Renofrin to be less effective.
- heart medicines containing digoxin or metoprolol, as your doctor may want to change the dose of this medicine whilst you are taking Renofrin.
- certain medicines to treat allergies (e.g. terfenadine, astemizole, mizolastine), heart rhythm disorders (e.g. disopyramide, procainamide) and depression (e.g. imipramine, doxepin, amitriptyline), as these medicines may affect your ECG.
- certain medicines to treat depression (bupropion), psychosis, HIV infection (efavirenz) or cancer (cyclophosphamide).
- certain medicines to treat high levels of cholesterol in the blood (e.g. simvastatin, lovastatin, atorvastatin). These medicines may cause muscle pain and muscle injury. Your doctor may decide to change the dose of this medicine while you are taking Renofrin.
- certain medicines used to prevent transplanted organ rejection (e.g. tacrolimus, ciclosporin, sirolimus, everolimus) as your doctor may decide to change the dose of this medicine while you are taking Renofrin.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Renofrin with food and drink

Renofrin can be taken with or without food. While being treated with Renofrin, you should not drink grapefruit juice.

Pregnancy

You should not take Renofrin if you are pregnant unless your doctor has advised you to do so.

Breast-feeding

You should not take Renofrin if you are breast-feeding. Ask your doctor for advice if you are breast-feeding.

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

Driving and using machines

No studies on the effects of Renofrin on the ability to drive and use machines have been performed. Ask your doctor for advice about driving or using machines.

Renofrin may cause side effects such as dizziness (common), blurred vision (uncommon), confusional state (uncommon), hallucination (uncommon), double vision (uncommon), coordination problems (rare), that may affect your ability to drive or use machines. If you experience these symptoms, do not drive or operate machinery until they have resolved completely.

Renofrin 750 mg prolonged-release tablets contain the azo colouring agent E102. This colouring agent may cause allergic reactions.

Renofrin 750 mg prolonged-release tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Renofrin

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

Always swallow the tablets whole with water. Do not crush, suck or chew the tablets or break them in half, as this might affect the way the medicine is released from the tablets into your body.

The starting dose for adults is one 375 mg tablet twice a day. After 2–4 weeks, your doctor may increase the dose to get the right effect. The maximum dose of Renofrin is 750 mg twice a day.

It is important that you tell your doctor if you get side effects such as dizziness or feeling or being sick. Your doctor may lower your dose or, if this is not sufficient, stop treatment with Renofrin.

Use in children and adolescents

Children and adolescents under 18 years old should not take Renofrin.

If you take more Renofrin than you should

If you accidentally take too many Renofrin tablets or take a higher dose than recommended by your doctor, it is important that you tell your doctor at once. If you cannot contact your doctor, go to the nearest accident and emergency department. Take along any tablets that are left, including the container and the carton, so that the hospital staff can easily tell what you have taken.

If you forget to take Renofrin

If you forget to take a dose, take it as soon as you remember unless it is nearly time (less than 6 hours) to take your next dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Renofrin and see your doctor immediately if you experience the following symptoms of angioedema, which is a rare condition but can be severe:

- swollen face, tongue or throat.
- difficulty swallowing.
- hives or difficulty breathing.

Tell your doctor if you experience common side effects, such as dizziness or feeling sick or vomiting. Your doctor may lower your dose or stop treatment with Renofrin.

Other side effects you may experience include the following:

Common side effects (occur in 1 to 10 users in 100) are:

- Constipation
- Dizziness
- Headache
- Feeling sick, vomiting
- Feeling weak

Uncommon side effects (occur in 1 to 10 users in 1,000) are:

- Altered sensation
- Anxiety, difficulty sleeping, confusional state, hallucination
- Blurred vision, visual disturbance
- Changes in sensation (touch or taste), tremor, feeling tired or sluggish, sleepiness or drowsiness, faint or fainting, dizziness upon standing
- Dark urine, blood in urine, difficulty urinating
- Dehydration
- Difficulty breathing, cough, nose bleed
- Double vision
- Excessive sweating, itching
- Feeling swollen or bloated
- Hot flushes, low blood pressure
- Increases in a substance called creatinine or increases in urea in your blood, increase in blood platelets or white blood cells, changes in ECG heart tracing
- Joint swelling, pain in extremity
- Loss of appetite and/or weight loss
- Muscle cramp, muscle weakness
- Ringing in the ears and/or feeling a spinning sensation
- Stomach pain or discomfort, indigestion, dry mouth or wind

Rare side effects (occur in 1 to 10 users in 10,000) are:

- A lack of ability to urinate
- Abnormal laboratory values for liver
- Acute kidney failure
- Change in sense of smell, numbness in mouth or lips, impaired hearing
- Cold sweat, rash
- Coordination problems
- Decrease in blood pressure upon standing
- Decreased or loss of consciousness
- Disorientation
- Feeling of coldness in hands and legs
- Hives, allergic skin reaction
- Impotence
- Inability to walk due to imbalance
- Inflammation of pancreas or intestine
- Loss of memory
- Throat tightness
- Low level of sodium in the blood (hyponatremia) which can cause tiredness and confusion, muscle twitching, cramps and coma

Not known side effects (frequency cannot be estimated from the available data) are:

- Myoclonus

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This include any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Renofrin

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

Do not use this medicine after the expiry date, which is stated on each blister strip of tablets and on the

outside of the carton after “EXP”.

Store in the original package to protect from light.

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 Renofrin contains

- The active substance in Renofrin is ranolazine.

Each tablet contains 375 mg, 500 mg or 750 mg ranolazine.

- The other ingredients are: methacrylic acid-ethyl acrylate copolymer (1:1) (type A), cellulose microcrystalline 101 (E460), hypromellose (2910), sodium hydroxide (E524), magnesium stearate (E470b).

Depending on the tablet strength, the tablet coatings contain:

375 mg tablet: hypromellose 2910 (E464), titanium dioxide (E171), macrogol 8000 (E1521), polysorbate 80 (E433), FD&C Blue#2/Indigotine, Aluminium Lake (E132).

500 mg tablet: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), macrogol 8000 (E1521), talc (E553b), yellow iron oxide (E172iii), red iron oxide (E172ii).

750 mg tablet: hypromellose 2910 (E464), lactose monohydrate, titanium dioxide (E171), triacetin (E1518), FD&C Yellow#5/Tartrazine Aluminum Lake (E102), FD&C Blue#1/FCF Fast Blue Aluminum Lake (E133).

What Renofrin looks like and contents of the pack

Renofrin prolonged-release tablets are oval shaped tablets.

The 375 mg tablets are pale blue and are engraved with “375” on one side.

The 500 mg tablets are light orange and are engraved with “500” on one side.

The 750 mg tablets are pale green and are engraved with “750” on one side.

Renofrin is supplied in carton boxes containing 30, 60 or 100 tablets in blisters.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Innovis Pharma S.A.

144 Marathonos Avenue

15351, Pallini, Attica, Griekenland

Tel: +30 216 200 5600

E-mail: info@innovispharma.gr

Manufacturer

ELPEN Pharmaceutical Co Inc

95 Marathonos Avenue

19009 Pikermi, Attica, Griekenland

In het register ingeschreven onder:

Renofrin 375 mg: RVG 129203

Renofrin 500 mg: RVG 129204

Renofrin 750 mg: RVG 129205

This medicine is authorised in the Member States of the European Economic Area under the

following names:

Netherlands, Greece: Renofrin

Deze bijsluiter is voor het laatst goedgekeurd in maart 2025.