Bijsluiter: informatie voor de patiënt

Ranolazine STADA 375 mg, tabletten met verlengde afgifte
Ranolazine STADA 500 mg, tabletten met verlengde afgifte
Ranolazine STADA 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 [product name] is and what is used for

[product name] 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 [product name] Do not take [product name]

- 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 [product name]:
- 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 [product name]
Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Do not use the following medicines if you take [product name]:
- 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 [product name] 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 [product name] (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 [product name] 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 [product name].
- 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 [product name].
- 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 [product name].

[product name] with food and drink
[product name] can be taken with or without food. While being treated with [product name], you should not drink grapefruit juice.

Pregnancy and 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.

Pregnancy
You should not take [product name] if you are pregnant unless your doctor has advised you to do so.

Breast-feeding
You should not take [product name] if you are breast-feeding. Ask your doctor for advice if you are breastfeeding.

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

[product name] 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.

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

3. How to take [product name]

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 [product name] 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 [product name].

Use in children and adolescents
Children and adolescents under 18 years old should not take [product name].

If you take more [product name] than you should
If you accidentally take too many [product name] 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 [product name]
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.

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.

You should stop taking [product name] 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 [product name].

Other side effects you may experience include the following:

Common side effects (may affect up to 1 in 10 people) are:
Constipation
Dizziness
Headache
Feeling sick, vomiting

Feeling weak

Uncommon side effects (may affect up to 1 in 100 people) 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 (may affect up to 1 in 1 000) 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 [product name]

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 package after "EXP".
The expiry date refers to the last day of that month.

This medicinal product 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 [product name] contains

The active substance in [product name] is ranolazine. Each tablet contains 375 mg, 500 mg, or 750 mg ranolazine.

The other ingredients are:
Tablet core: microcrystalline cellulose (E460), methacrylic acid-ethyl acrylate copolymer (1:1), sodium hydroxide (E524), hypromellose (E464), magnesium stearate (E470b).

Film-coating system AquaPolish P white: hypromellose (E464), hydroxypropylcellulose (E463), macrogol 8000 (E1521), titanum dioxide (E171).

What [product name] looks like and contents of the pack
The 375 mg tablets are white, oblong, convex, film-coated tablet of dimensions 15 mm x 7.2 mm, with "375" embossed on one side.
The 500 mg tablets are white, oblong, convex, film-coated tablet of dimensions 16.5 mm x 8.0 mm, with "500" embossed on one side.
The 750 mg tablets are white, oblong, convex, film-coated tablet of dimensions 19 mm x 9.2 mm, with "750" embossed on one side.

[product name] is supplied in cardboard boxes containing 30, 60 or 100 tablets in PVC/PVDC/Aluminium blisters.

Not all pack-sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
STADA Arzneimittel AG
Stadastrasse 2-18
Bad Vilbel, 61118
Duitsland

Fabrikant:
Adamed Pharma S.A.
Ul. Marszałka Józefa Piłsudskiego 5
Pabianice 95-200
Polen

In het register ingeschreven onder:

Ranolazine STADA 375 mg, tabletten met verlengde afgifte	RVG 128890
Ranolazine STADA 500 mg, tabletten met verlengde afgifte	RVG 128891
Ranolazine STADA 750 mg, tabletten met verlengde afgifte	RVG 128892

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland	Ranolazine STADA, 375 mg, 500 mg, 750 mg, tabletten met verlengde afgifte
Estland	Ranolazine STADA
Duitsland	Ranolazin AL 375 mg, 500 mg, 750 mg Retardtabletten
Ierland	Ranolazine Clonmel 375 mg, 500 mg, 750 mg prolonged-release tablets
Italië	Ranolazina EG
Letland	Ranolazine STADA 275 mg, 500 mg, 750 mg ilgstošās darbības tablete
Litouwen	Ranolazine STADA 375 mg, 500 mg, 750 mg pailginto atpalaidavimo tabletės
Portugal	Ranolazina Ciclum
Slovenië	Ranolazin STADA 375 mg, 500 mg, 750 mg tablete s podaljšanim sproščanjem
Spanje	Ranolazina STADA 375 mg, 500 mg, 750 mg Comprimido de liberación prolongada EFG

Deze bijsluiter is voor het laatst goedgekeurd in juli 2022.