Package leaflet: Information for the user

Vastarel 35 mg Modified-Release Tablets
Trimetazidine dihydrochloride

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 toyour doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
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What is in this leaflet:

1. What Vastarel 35 mg Modified-Release Tablets is and what it is used for

This medicine is intended for use in adult patient, in combination with other medicines to treat angina pectoris (chest pain caused by coronary disease).
It protects the heart cells from the effects of a reduced oxygen supply during an episode of angina.

2. What you need to know before you take Vastarel 35 mg Modified-Release Tablets

Do not take Vastarel 35 mg Modified-Release Tablets
- if you are allergic to trimetazidine or any of the other ingredients of this medicine (listed in section 6),
- if you have a Parkinson disease: disease of the brain affecting movement (trembling, rigid posture, slow movements and a shuffling, unbalanced walk),
- if you have severe kidney problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Vastarel 35 mg Modified-Release Tablets
This drug is not a cure for angina attacks, and should not be used as a treatment for unstable angina or heart attack.

In the event of an angina attack, tell your doctor. Your treatment should be re-evaluated.

This medicine can cause or worsen symptoms such as trembling, rigid posture, slow movements and a shuffling, unbalanced walk, especially in elderly patients, which should be investigated and reported to your doctor who could reassess the treatment.

Take special care with Vastarel 35 mg Modified-release Tablets if you have a problem with increased pressure in your eyes (close-angle glaucoma).

Athletes:
This medicine contains an active substance which may give a positive reaction in doping tests.

Children and adolescents
Vastarel 35 mg Modified-Release Tablets is not recommended in children aged below 18 years.

Other medicines and Vastarel 35 mg Modified-Release Tablets
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
As a precautionary measure, it is preferable not to take Vastarel 35 mg Modified-Release Tablets during pregnancy.

In the absence of data on excretion in breast milk, breast-feeding is not indicated during treatment with Vastarel 35 mg Modified-Release Tablets.

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
This medicine may make you feel dizzy and drowsy that may affect your ability to drive or use machinery.

3. How to take Vastarel 35 mg Modified-Release Tablets

Always take Vastarel 35 mg Modified-Release Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Adults:

The recommended dose of Vastarel 35 mg Modified-Release Tablets is one tablet to be taken two times a day during meals in the morning and evening. Swallow your tablets whole. Do not chew them.

Patients with kidney disease and elderly
If you have kidney problems or if you are older than 75 years old, your doctor may adjust the recommended dose.
For patients with severe kidney disease: not recommended.

Children:

Not recommended for children.

If you take more Vastarel 35 mg Modified-Release Tablets than you should
If you take too many tablets, please contact your doctor or the nearest hospital Emergency Department immediately.

If you forget to take Vastarel 35 mg Modified-Release Tablets
If you forget to take one or more doses, do not take a double dose to make up for a forgotten dose.

If you stop taking Vastarel 35 mg Modified-Release Tablets
You should discuss with your doctor before you stop taking your tablets. 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.

Common (may affect up to 1 in 10 people):
Dizziness, headache, abdominal pain, diarrhoea, indigestion, feeling sick, vomiting, rash, itching, hives and feeling of weakness.

Rare (may affect up to 1 in 1,000 people):
Fast or irregular heartbeats (also called palpitations), extra heartbeats, faster heartbeat, fall in blood pressure on standing-up which causes dizziness, light headiness or fainting, malaise (generally feeling unwell), dizziness, fall, flushing.

Not known (frequency cannot be estimated from the available data):
Extrapyramidal symptoms (unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs), usually reversible after treatment discontinuation.

Sleep disorders (difficulty in sleeping, drowsiness), spinning sensation (vertigo), constipation, serious generalised red skin rash with blistering, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

Severe reduction in number of white blood cells which makes infections more likely, reduction in blood platelets, which increases risk of bleeding or bruising.
A liver disease (nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine).

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. You can also report side effects directly via:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vastarel 35 mg Modified-Release Tablets

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.

If your doctor decides to stop your treatment, return any tablets left over to the pharmacist. Only keep them if your doctor tells you to.

Do not use this medicine after the expiry date , which is stated on the blister and on the carton after EXP. 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 dispose of medicines you no longer use. These measures will help to protect the environment

6. Further information

What Vastarel 35 mg Modified-Release Tablets contains
The active substance is trimetazidine dihydrochloride. Each tablet of Vastarel 35 mg Modified-Release Tablets contains 35 mg trimetazidine dihydrochloride.

The other ingredients are: calcium hydrogen phosphate dihydrate, hypromellose, hypromellose 4000, povidone, anhydrous colloïdal silica, magnesium stearate, macrogol 6000, titanium dioxide (E171), glycerol, red iron oxide (E172).

What Vastarel 35 mg Modified-Release Tablets looks like and the contents of the pack

Vastarel 35 mg Modified-Release Tablets are presented as pink round film-coated tablets which are supplied in packs of 10, 30, 60 and 90 tablets. Not all of these pack sizes may be marketed.

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This leaflet was last revised in February 2021