

VASTAREL MR

Trimetazidine dihydrochloride, 35mg

What is in this leaflet

1. What VASTAREL MR is used for
2. How VASTAREL MR works
3. Before you use VASTAREL MR,
4. How to use VASTAREL MR,
5. While you are using it
6. Side effects
7. Storage and Disposal of VASTAREL MR
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What VASTAREL MR is used for

Vastarel MR contains an active ingredient called trimetazidine dihydrochloride. It belongs to a group of medicines called antiangina.

Trimetazidine is indicated in adults as add-on therapy for the symptomatic treatment of patients with chest pain (stable angina pectoris) who are inadequately controlled by or intolerant to first-line antianginal therapies.

How VASTAREL MR works

Trimetazidine acts by inhibiting the breakdown of fatty acids which enhances glucose oxidation. Glucose oxidation requires less oxygen consumption thus optimises the heart's energy producing function, protecting vulnerable heart muscle tissues from further oxygen-deprived damage.

Before you use VASTAREL MR

- When you must not use it

Do not take VASTAREL MR:

- if you are allergic to trimetazidine or any of the other ingredients of this medicine (listed in section 8),
- 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.

- Before you start to use it

Talk to your doctor or pharmacist before taking VASTAREL MR. This medicinal product is generally not recommended during breastfeeding.

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

This medicinal product is not a curative treatment for chest pain (angina attacks), nor an initial treatment for unstable angina pectoris. It is not a treatment for heart attack (myocardial infarction).

In the event of an chest pain (angina attack), inform your doctor. Tests may be required and your treatment may possibly be modified.

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.

Children

VASTAREL MR is not recommended in children aged below 18 years.

- Taking other medicines

You must inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, even if it is a medicine that you can buy without a prescription.

How to use VASTAREL MR

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

Vastarel MR is to be taken orally.

- How much to use

The recommended dose of VASTAREL MR is one tablet to be taken two times a day during meals in the morning and evening.

If you have kidney problems or if you are older than 75 years old, your doctor may adjust the recommended dose.

- When to use it

The tablets should be swallowed with a glass of water at mealtimes.

- How long to use it

Continue taking VASTAREL MR for as long as your doctor recommends.

Your doctor might assess your treatment benefit after three

months and if there is no response, trimetazidine should be discontinued.

- If you forget to use it

It is important to take your medicine every day as regular treatment works better.

However, if you forget to take a dose of VASTAREL MR take one tablet with the next meal. Do not take a double dose to compensate the single dose you have forgotten to take.

- If you use too much (overdose)

Consult a doctor or a pharmacist immediately.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking VASTAREL MR.

It is preferable not to take this medicine during pregnancy. If you discover that you are pregnant whilst taking this medicine, consult your doctor as he alone can judge the necessity of continuing your treatment.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give VASTAREL MR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

Falls may occur following a drop in blood pressure or a loss of balance (see description of side effects)

Side Effects

As with all medicines, VASTAREL MR is likely to have side effects, although not everyone may be prone to them.

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

Common:

Dizziness, headache, abdominal pain, diarrhoea, indigestion, feeling sick, vomiting, rash, itching, hives and feeling of weakness.

Rare:

Fast or irregular heartbeats (also called palpitations), extra heartbeats, faster heartbeat, fall in blood pressure on standing-up which causes dizziness, light headedness or fainting, malaise (generally feeling unwell), dizziness, fall, flushing.

Not known:

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), 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).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of VASTAREL MR

- Storage

Keep out of the reach and sight of children.

Do not use VASTAREL MR after the expiry date which is

stated on the carton and the blister strip. The expiry date refers to the last day of that month.

Do not use VASTAREL MR if you note signs of deterioration on the packaging or on blisters.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like:

VASTAREL MR, modified release is in the form of pink, film-coated lenticular tablet available in a box 60 tablets.

- Ingredients

- Active ingredient:
Trimetazidine dihydrochloride. One tablet contains 35 mg of Trimetazidine dihydrochloride.
- Inactive ingredients:
Calcium hydrogen phosphate dehydrate; hypromellose; povidone; anhydrous colloidal silica, magnesium stearate;
Film-coating: titanium dioxide (E 171), glycerol, hypromellose, macrogol 6000, red iron oxide (E 172), magnesium stearate

- MAL number:

MAL20051401A
MAL09011457ACS

Manufacturer

Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy
France
for Vastarel MR
(MAL20051401A)

Kotra Malaysia Sdn Bhd
No.1, 2& 3, Jalan TTC 12
Cheng Industrial Estate
75250 Melaka
Malaysia
for Vastarel MR
(MAL09011457ACS)

Product registration holder

Servier Malaysia Sdn Bhd
1301 Level 13, Uptown 2
No 2 Jalan SS 21/37,
Damansara Uptown
47400 Petaling Jaya
Selangor

Date of revision

15.04.2015

Serial Number

BPFK(R4/1)140415/00067