VASTAREL MR

Trimetazidine dihydrochloride, 35mg

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What VASTAREL MR is used for

OTHER CARDIAC PREPARATIONS - ATC code: C01EB15

This medicine is intended for use in adult patients, in combination with other medicines to treat angina pectoris (chest pain caused by coronary disease).

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 not a curative treatment for angina attacks, nor an initial treatment for unstable angina. It is not a treatment for 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.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with VASTAREL MR. Stop using VASTAREL MR and seek medical attention immediately if you notice any of the symptoms related to this serious skin reaction described in section 6.

This medicinal product is generally not recommended during breastfeeding.

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

Athletes
VASTAREL MR contains an active substance that may give a positive result in anti-doping tests.

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

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines.

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*

ALWAYS USE EXACTLY AS INDICATED IN YOUR DOCTOR'S PRESCRIPTION.

- *If you forget to use it*

Resume treatment normally. Do not take a double dose to make up for a forgotten dose.

- *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 phamacists 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*

Pregnancy and breastfeeding

Pregnancy

It is preferable not to use this medicine during pregnancy. If you discover that you are pregnant whilst taking this medicine, consult your doctor.

Breastfeeding

In the absence of data on excretion in breast milk, VASTAREL must not be used while 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.

Driving and using machines

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

Side Effects

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

Stop using VASTAREL MR and immediately contact a doctor if you notice any of the following side effects:

Not known: frequency cannot be estimated from the available data

• Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS). See also section 2.

• Serious generalized red skin rash with blistering

The following side effects have been described:

Common *(occurring in fewer than 1 in 10 patients)*:

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

Uncommon side effects: may affect up to 1 in 100 people

• unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

Rare *(occurring in fewer than 1 in 1,000 patients)*:

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

Not known *(the 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), dizziness, constipation, 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.

Liver disease (nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured stools, 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of VASTAREL MR

- *Storage*

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

Do not use this medicine after the expiry date which is stated on the

packaging. The expiry date refers to the last day of that month.

Store below 30°C.

- *Disposal*

Do not throw away any medicines 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 modified-release film-coated tablet contains 35 mg of Trimetazidine dihydrochloride.
- Inactive ingredients: Calcium hydrogen phosphate dihydrate; 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:*

MAL20051401AZ
MAL09011457ACSZ

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