Package leaflet: Information for the patient

VASTAREL MR® 35mg

Trimetazidine Dihydrochloride
(Modified-Release Film-Coated Tablet)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for your treatment.
- 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 of the side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

What is in this leaflet

1. WHAT VASTAREL 35 mg, modified-release film-coated tablet IS AND WHAT IT 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).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VASTAREL 35 mg, modified-release film-coated tablet

Do not take VASTAREL 35 mg, modified-release film-coated tablet:

- If you are allergic to trimetazidine or any of the other ingredients of this medicine (listed in section 6).
- If you have Parkinson's 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 film-coated tablet.
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 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.
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
This medicine contains an active substance that may give a positive result in anti-doping tests.

Children and adolescents

VASTAREL 35 mg, modified-release film-coated tablet must not be administered to children aged below 18 years.

Other medicines and VASTAREL 35 mg, modified-release film-coated tablet

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

VASTAREL 35 mg, modified-release film-coated tablet with food and drink

Not applicable.

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, which may affect your ability to drive or use machinery.

VASTAREL 35 mg, modified-release film-coated tablet contains:

not applicable.

3. HOW TO TAKE VASTAREL 35 mg, modified-release film-coated tablet

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

Dosage

The recommended dose of VASTAREL 35 mg, modified-release film-coated tablet 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.

Duration of treatment

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

If you take more VASTAREL 35 mg, modified-release film-coated tablet than you should:

Consult your doctor or pharmacist immediately.

If you forget to take VASTAREL 35 mg, modified-release film-coated tablet:

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

If you stop taking VASTAREL 35 mg, modified-release film-coated tablet:

Not applicable.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been described:

Common (occurring in fewer than 1 in 10 patients):
Dizziness, headache, abdominal pain, diarrhoea, indigestion, feeling ill, vomiting, rash, itching, hives and feeling of weakness.

Rare (occurring in fewer than 1 in 1,000 patients):
Fast or irregular heartbeat (also called palpitations), extra heartbeats, faster heartbeat, fall in blood pressure on standing up, which can cause dizziness or fainting, malaise (generally feeling unwell), 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, severe generalised red skin rash with blistering, swelling of the face, lips, 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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Drug Regulatory Authority of Pakistan www.dra.gov.pk or to company website www/servier.com.pk
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 film-coated tablet

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 packaging. 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 VASTAREL 35 mg, modified-release film-coated tablet contains

- The active substance is:

Trimetazidine dihydrochloride ..... 35.00 mg
For one film-coated tablet.

- The other ingredients are:

Calcium hydrogen phosphate dihydrate, hypromellose, povidone, anhydrous colloidal silica, magnesium stearate.

Film-coating: titanium dioxide (E171), glycerol, hypromellose, macrogol 6000, red iron oxide (E172), magnesium stearate.

What VASTAREL 35 mg, modified-release film-coated tablet looks like and contents of the pack

This medicinal product is supplied in the form of film-coated tablets.
Pack of 20 Tablets.

Marketing authorisation holder

Servier Research and Pharmaceuticals [Pakistan](Pvt)Ltd
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Date of Revision of Text : May 2021

04043
Version-04

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