

VASTAREL MR® 35mg

Trimetazidine Dihydrochloride
(Film-Coated Tablet)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What VASTAREL MR 35mg, film-coated tablet is and what it is used for?
2. Before you take VASTAREL MR 35mg, film-coated tablet
3. How to take VASTAREL MR 35mg, film-coated tablet
4. Possible side effects
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1. WHAT VASTAREL MR 35mg, film-coated tablet IS AND WHAT IT IS USED FOR?

OTHER CARDIOLOGICAL ANTI-ANGINAL DRUGS

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

2. NECESSARY INFORMATION WHAT YOU NEED TO KNOW BEFORE YOU TAKE VASTAREL MR 35mg, film-coated tablet:

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

- If you are allergic to trimetazidine or to any of the other ingredients of this medicine VASTAREL MR 35mg, film-coated tablet. (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.

Take special care with VASTAREL MR 35mg, film-coated tablet:

Talk to your doctor or pharmacist before taking VASTAREL MR 35mg, film-coated tablet.

This medicinal product is generally not recommended during breast-feeding.

This medicinal product is not a curative treatment for angina attacks, nor an initial treatment for unstable angina pectoris. 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.

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

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.

Children and adolescents

VASTAREL MR 35mg, film-coated tablet is not recommended in children aged below 18 years.

Pregnancy and breast-feeding

Pregnancy

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.

Breast-feeding

In the absence of data on excretion in breast milk, breast-feeding is not recommended during treatment.

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 MR 35mg, 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.

The recommended dose of VASTAREL MR 35mg, 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.

Dosage:

IN ALL CASES STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION

Method and route of administration:

Oral administration

Frequency and time at which time the drug should be taken:

Tablets should be taken with a glass of water at meal times

Duration of treatment:

IN ALL CASES STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION

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

Inform your doctor or pharmacist.

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

Resume treatment normally.

Do not double the dose the day after you miss a dose.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

As with all medicines, VASTAREL MR 35mg, film-coated tablet 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 1000)

Rare (affects 1 to 10 users in 10000)

Very rare (affects less than 1 user in 10000)

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.

5. HOW SHOULD VASTAREL MR 35mg, film-coated tablet BE STORED?

Keep out of the reach and sight of children.

Do not use VASTAREL MR 35mg, film-coated tablet, after the expiry date stated on the box.

Protect from direct light, heat & moisture.

Protect from humidity.

6. FURTHER INFORMATION

What VASTAREL MR 35mg, film-coated tablet contains?

the active substance is:

Trimetazidine dihydrochloride 35.00 mg

For one film-coated tablet.

the other ingredients are:

Nucleus: calcium hydrogen phosphate dihydrate, magnesium stearate, hypromellose, silica colloidal anhydrous, povidone K-30.

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

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

This medicine is in the form of film-coated tablets. Box of the 20 tablets.



Manufactured by:

Servier Research & Pharmaceuticals (Pakistan) (Pvt) Ltd.

9-km Sheikhupura Road, Lahore - Pakistan

Under Licence Les Laboratoires Servier - France