

VASTAREL[®] XR 80MG

Trimetazidine dihydrochloride 80mg, prolonged-release hard capsule

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What VASTAREL XR is used for

VASTAREL XR is intended for use in adults, in combination with other medicines to treat angina pectoris (chest pain caused by coronary disease).

How VASTAREL XR works

VASTAREL XR contains an active ingredient, trimetazidine dihydrochloride. It 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 XR

When you must not use it

Do not take VASTAREL XR if you:

- are allergic to trimetazidine or any of the other ingredients of this medicine (listed in ingredients section),
- have a Parkinson disease: disease of the brain affecting movement (trembling, rigid posture, slow movements and a shuffling, unbalanced walk),
- have severe kidney problems.

Before you start to use it

Warnings and precautions

Talk to your doctor or pharmacist before taking VASTAREL XR.

This drug is not a curative treatment for angina attacks, nor an initial treatment for unstable angina or heart attack (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 Parkinsonian 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 XR. Stop using VASTAREL XR and seek medical attention immediately if you notice any of the symptoms related to this serious skin reaction described in section 6.

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

VASTAREL XR contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Athletes

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

Children and adolescents

VASTAREL XR is not recommended for use in children and adolescents younger than 18 years.

Pregnancy and breast-feeding

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

In the absence of data on excretion in human breast milk, you should not take VASTAREL XR during breastfeeding.

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.

Taking other medicines

No drug interaction has been identified. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

How to use VASTAREL XR

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

How much to use

The recommended dose is one capsule to be taken once a day during breakfast.

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

VASTAREL XR is for oral use. The capsules are to be swallowed whole, without opening them, with a glass of water at breakfast.

How long to use it

Your doctor will tell you how long the treatment will last. You should discuss with your doctor before stopping this medicinal product.

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 your medicine, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

If you may have taken more capsules than you should, consult a doctor or a pharmacist immediately.

While you are using it

Things you must do

Always take this medicine exactly as your doctor/pharmacist has told you.

Inform the doctors, dentists and pharmacists treating you that you are taking VASTAREL XR.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Things you must not do

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

Do not take any new medicines without consulting your doctor.

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.

Things to be careful of

VASTAREL XR with food and drink

This medicine can be taken with food and drink.

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

- very common (may affect more than 1 in 10 people)

- common (may affect up to 1 in 10 people)

- uncommon (may affect up to 1 in 100 people)

- rare (may affect up to 1 in 1000 people)

- very rare (may affect up to 1 in 10,000 people)

- not known (cannot be estimated from the available data)

Common:

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

Uncommon:

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

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) or fall, flushing.

Not known:

Parkinsonian 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 allergic reaction (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

Tell your doctor/pharmacist if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of VASTAREL XR. Consult your doctor/pharmacist for further information.

Call your doctor for medical advice about side effects. 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 XR

Storage

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 carton and blister. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions. Store below 30°C.

Disposal

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.

Product description

What it looks like

VASTAREL XR prolonged-release hard capsules are with a white body and an orange red cap with a printed in white Servier logo  on it.

The capsules are available in packs (polyamide-aluminium-PVC/Aluminium blisters) of 10 or 30 capsules.

Not all packs sizes may be marketed.

Ingredients

- Active ingredients:

The active substance is trimetazidine (as dihydrochloride) One prolonged-release hard capsule contains 80 mg of trimetazidine.

- Other ingredients:

Capsule content:

Sugar sphere containing sucrose and maiz starch

Hypromellose

Ethylcellulose

Tributyl acetylcitrate

Talc

Magnesium stearate

Capsule shell:

Gelatin

Titanium dioxide (E171),

Red iron oxide (E172),

Printing Ink:

Shellac Glaze-45% in Ethanol

Titanium dioxide (E171)

Simethicone

Propylene Glycol (E1520)

Ammonium hydroxide 28% (E527)

MAL number:

MAL19126006AZ

Manufacturer

Egis Pharmaceuticals PLC

Production site of Körmend

H-9900 Körmend

Mátyás Király u 65

Hungary

Product registration holder

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Selangor Darul Ehsan

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