

VASTAREL 20 mg

Trimetazidine dihydrochloride (20mg)

What is in this leaflet

1. What VASTAREL 20 mg is used for
2. How VASTAREL 20 mg works
3. Before you use VASTAREL 20 mg
4. How to use VASTAREL 20 mg
5. While you are using it
6. Side effects
7. Storage and Disposal of VASTAREL 20 mg
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What VASTAREL 20 mg is used for

OTHER CARDIOVASCULAR ANTIANGINAL DRUG - 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).

How VASTAREL 20 mg works

Trimetazidine acts by inhibiting the break down of fatty acids which enhances glucose oxidation. Energy obtained during glucose oxidation requires less oxygen consumption thus optimises the heart's energy producing function, protecting vulnerable heart muscle tissue from further oxygen-deprived damage.

Before you take VASTAREL 20 mg

- When you must not use it

Do not take VASTAREL 20 mg:

- 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 20 mg.
- This medicinal product is not a curative treatment for chest pain, nor an initial treatment for unstable angina pectoris (a type of chest pain). It is not a treatment for heart attack.
- In the event of chest pain, 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 20 mg, film-coated tablet. Stop using VASTAREL 20 mg, film-coated tablet 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 breast-feeding.
- Falls may occur following a drop in blood pressure or a loss of balance (see description of side effects).
- This medicine contains sunset yellow FCF S (E110) and cochineal red A (E 124) and may cause allergic reactions.

Athletes

VASTAREL 20 mg contains an active substance that may give a positive result in anti-doping tests.

Children and adolescents

VASTAREL 20 mg tablet must not be administered to children aged below 18 years.

- Taking other medicines

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

How to use VASTAREL 20 mg

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

- How much to use

The recommended dose of VASTAREL 20 mg is one tablet to be taken three times a day during meals.

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

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

- How long to use it

In all cases strictly comply with your doctor's prescription.

- If you forget to use it

Resume treatment normally.
Do not take a double dose to compensate for the single dose you forgot 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.

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.

Tell all the doctors, dentists and pharmacists treating you that you are taking VASTAREL 20 mg.

Tell your doctor immediately if you become pregnant while taking this medication.

- 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 20 mg to anyone else, even if they have

the same symptoms or condition as you.

- Things to be careful of

Pregnancy and breast-feeding

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.

Breast-feeding

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

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.

VASTAREL 20 mg, film-coated tablet contains sunset yellow FCF (E110) and cochineal red A (E124).

Side effects

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

Stop using VASTAREL 20 mg, film-coated tablet 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 3.

- 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 1000 patients):

Fast or irregular heartbeats (also called palpitations), extra heartbeats, faster heartbeat, fall in blood pressure on standing-up which causes dizziness (spinning head), light headedness 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), spinning sensation (vertigo), 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 bowel motions, dark coloured urine).

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 20 mg

- Storage

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

Do not use this medicine after the expiry date stated on the box. 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:

This medicine is in the form of film-coated tablets. Available in a box of 60 tablets.

- Ingredients

- Active ingredient: Trimetazidine dihydrochloride. One film-

coated tablet contains 20 mg of Trimetazidine dihydrochloride.

- Inactive ingredients: maize starch, mannitol, povidone, magnesium stearate, talc.

Film-coating: Mixture of excipients for red coating 37771 FRG (titanium dioxide (E 171), glycerol, aluminium lake of sunset yellow FCF S (E110), aluminium lake of cochineal red A (E 124), macrogol 6000, hypromellose, magnesium stearate), macrogol 6000.

Registration number

MAL19870169AZ

Manufacturer

Les Laboratoires Servier
Industrie
905 route de Saran
45520 Gidy - France

Product Registration Holder

Servier Malaysia Sdn Bhd
Unit No.25-02, Level 25,
Imazium
No.8, Jalan SS21/37, Damansara
Uptown
47400 Petaling Jaya, Selangor
Darul Ehsan

Date of revision

03.12.2024

Serial Number

NPRA (R1/3) 12022025/032