

VASTAREL 20 mg

Trimetazidine dihydrochloride (20mg)

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What VASTAREL 20 mg is used for

Vastarel belongs to a group of medicines called anti-anginal. It is used as an add-on treatment for patient with chest pain (stable angina pectoris).

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 tablet

- 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 generally not recommended during breastfeeding and pregnancy. Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding or intend to become pregnant.
- 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 medicinal product contains sunset yellow FCF S (E110) and cochineal red A (E 124) and may cause allergic reactions.
- Please let your doctor knows before you start to take this medicine if you have history of allergy to some colouring agents.

Children

VASTAREL 20 mg is not recommended in children aged below 18 years.

- 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.

Always refer to a doctor or pharmacist before you take any other medicines.

How to use VASTAREL 20 mg

Always take VASTAREL 20 mg exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Vastarel is to be taken orally.

- 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.

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

- 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

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

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

Side effects

As with all medicines, VASTAREL 20 mg 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 1,000)
- Rare (affects 1 to 10 users in 10,000)
- Very rare (affects less than 1 user in 10,000)
- 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 headiness 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of VASTAREL 20 mg

- Storage

Keep out of the reach and sight of children.

Do not use VASTAREL 20 mg after the expiry date stated on the box.

Protect from humidity.

Store below 30°C.

- Disposal

Medicines should not be disposed of 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 contains 20 mg of Trimetazidine dihydrochloride.
- Inactive ingredients:
Nucleus: maize starch, mannitol, povidone, magnesium stearate, talc.
Film-coating: excipients mixture 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.

Product Registration Holder

Servier Malaysia Sdn Bhd
1301 Level 13, Uptown 2
No 2 Jalan SS 21/37,
Damansara Uptown
47400 Petaling Jaya
Selangor Darul Ehsan

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Manufacturer

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