

Package leaflet: Information for the patient

Vastarel® OD 40 mg, prolonged-release hard capsule

Vastarel® OD 80 mg, prolonged-release hard capsule

Trimetazidine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Vastarel® OD is and what it is used for
2. What you need to know before you take Vastarel® OD
3. How to take Vastarel® OD
4. Possible side effects
5. How to store Vastarel® OD
6. Contents of the pack and other information

1. What Vastarel® OD is and what it is used for

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. What you need to know before you take Vastarel® OD

Do not take Vastarel® OD

- if you are allergic to trimetazidine or any of the other ingredients of this medicine (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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vastarel® OD

This drug 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).

Children and adolescents

Vastarel® OD is not recommended in children aged below 18 years.

Other medicines and Vastarel® OD

No drug interaction has been identified.

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

Vastarel® OD with food and drink

Vastarel® OD can be taken with food and drink.

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, consult your doctor as he alone can judge the necessity of continuing your treatment.

In the absence of data on excretion in breast milk, you should not take Vastarel® OD 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.

Driving and using machines

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

Vastarel® OD contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Vastarel® OD

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® OD 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.

Vastarel® OD is for oral use. The capsules are to be swallowed, without opening them, with a glass of water at breakfast.

If you take more Vastarel® OD than you should:

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

If you forget to take Vastarel® OD :

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 stop taking Vastarel® OD :

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

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

4. Possible side effects

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

Common: (may affect up to 1 in 10 people)

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

Rare (may affect up to 1 in 1000 people)

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) or fall, flushing.

Frequency unknown:

- 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.
- Spinning sensation (vertigo).
- 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 to store Vastarel® OD

Keep this medicine out of the sight and reach of children

Do not take this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 30°C.

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® OD 40 mg, prolonged-release hard capsule contains

The active substance is trimetazidine (as dihydrochloride)

One prolonged-release hard capsule contains 40 mg of trimetazidine dihydrochloride

The other ingredients are:

Capsule content:

Sugar sphere containing sucrose and maiz starch

Hypromellose

Ethylcellulose

Tributyl acetylcitrate

Talc

Magnesium stearate

Capsule shell:

Gelatin

Titanium dioxide (E171),

Printing Ink

Shellac (E904)

Titanium dioxide (E171)

Iron oxide black (E172)

Potassium hydroxide (E525)

Propylene Glycol (E1520)

Ammonium hydroxide 28% (E527)

What Vastarel® OD 80 mg, prolonged-release hard capsule> contains

The active substance is trimetazidine (as dihydrochloride)

One prolonged-release hard capsule contains 80 mg of trimetazidine dihydrochloride.

The other ingredients are:

Capsule content:

Sugar sphere containing sucrose and maize starch

Hypromellose

Ethylcellulose

Tributyl acetylcitrate

Talc

Magnesium stearate

Capsule shell:

Gelatin

Titanium dioxide (E171),

Red iron oxide (E172),

Printing Ink

Shellac (E904)

Titanium dioxide (E171)

Simethicone

Propylene Glycol (E1520)

Ammonium hydroxide 28% (E527)

What Vastarel® OD looks like and contents of the pack

Vastarel® OD 40 mg, prolonged-release hard capsule

Vastarel® OD prolonged-release hard capsules are with a white body and a white cap with a printed on grey Servier logo  and “40” on it.

Vastarel® OD 80 mg, prolonged-release hard capsule

Vastarel® OD prolonged-release hard capsules are with a white body and an orange red cap with a printed on white Servier logo  and “80” on it.

The capsules are available in polyamide-aluminium-PVC/Aluminium blisters in cartons containing 30, 60 or 90 prolonged release hard capsules.

Not all packs sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Les Laboratoires Servier

50 rue Carnot

92284 Suresnes cedex

France

Manufacturer

EGIS Pharmaceuticals PLC

H-1165 Budapest, Bökényföldi ut 118-120

Hungary

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in 06.2017