Package leaflet: information for the user

Vastarel® 20mg film-coated tablets

(trimetazidine dihydrochloride)

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.

The name of your medicine is Vastarel 20mg film-coated tablets but will be referred to as Vastarel throughout this leaflet.

In this leaflet

1. What Vastarel 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). It protects the heart cells from the effects of a reduced oxygen supply during an episode of angina.

2. What you need to know before you take Vastarel

Do not take Vastarel 20

- 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.

This drug is not a cure for angina attacks and should not be used as a treatment for unstable angina or heart attack.

In the event of an angina attack, tell your doctor. Your treatment should be re-evaluated.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Children and adolescents

Vastarel is not recommended in children aged below 18 years.

Pregnancy and breast-feeding

As a precautionary measure, it is preferable not to take Vastarel during pregnancy or 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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of your medicine

Your medicine contains Ponceau 4R aluminium lake (E 124) and sunset yellow FCF aluminium lake (E110) which may cause allergic reactions.

3. How to take Vastarel

Always take Vastarel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage

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

Children: Not recommended for children.

Patients with kidney disease and elderly patients: If you have kidney problems or if you are older than 75 years old, your doctor may adjust the recommended dose.

For patients with severe kidney disease: not recommended.

If you forget to take Vastarel 20mg

If you forget to take one or more doses, do not take a double dose to make up for a forgotten dose.

If you take more Vastarel than you should

If you take too many tablets, please contact your doctor or the nearest hospital Emergency Department immediately.

If you stop taking Vastarel
You should discuss with your doctor before you stop taking your tablets. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Vastarel can cause side effects, although not everybody gets 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 10 000
Very rare: affects less than 1 user in 10 000
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.

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).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vastarel

Keep out of the reach and sight of children.

Do not take Vastarel after the expiry date which is stated on the carton/ blister label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 30°C.

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

6. Further information

What Vastarel contains
Each film-coated tablet contains 20mg trimetazidine.
The other ingredients are: mannitol, maize starch, talc, povidone, magnesium stearate, glycerol, hypromellose, macrogol 6000, ponceau 4R aluminium lake (E124), sunset yellow aluminium lake (E110) and titanium dioxide.

What Vastarel looks like and the contents of the pack
Vastarel are round, red film-coated tablets supplied in blister packs containing 60 tablets.

Manufactured by: Vianex SA, Factory B,15th km Marathon Avenue, 153 51 Pallini Attica, Greece.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Vastarel 20mg film-coated tablets **POM**
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