Package leaflet: Information for the patient

Pretimectal 35 mg modified-release tablets

(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 Pretimectal 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 Pretimectal

Do not take Pretimectal
- 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 Pretimectal.

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.

Children and adolescents
Pretimectal is not recommended in children aged below 18 years.

Other medicines and Pretimectal
So far no reports of drug interactions.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Pretimectal with food, drinks and alcohol
The tablets should be taken with a glass of water with a meal.

Pregnancy, breast-feeding and fertility

Pregnancy
As a precautionary measure, it is preferable not to take this medicines during pregnancy.

If you are pregnant, while taking this medicine, talk to your doctor, as only he or she can assess the need for continued therapy.

Breast-feeding
Due to the lack of radiation data in breast milk, it is not recommended to take this medicine during 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
Pretimectal may make you feel dizzy and drowsy that may affect your ability to drive or use machinery.

3. How to take Pretimectal

Dosage
Always take this medicines exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Pretimectal 35 mg is one tablet to be taken two times a day – morning and evening, during meals.

If you have kidney problems or if you are older than 75 years old, your doctor may adjust the recommended dose.

Начин и пътища на приложение
Oral administration.
The tablets should be swallowed with a glass of water with a meal.

Frequency of administration
The recommendet dose is one tablet in the morning and evening.

If you have the impression that the effect of Pretimectal is too strong or too weak, talk to your doctor or pharmacist.

If you take more Pretimectal than you should
Consult your doctor or pharmacist immediately.

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

If you stop taking Pretimectal
Not applicable.

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;
- feeling of weakness.

Rare (may affect up to 1 in 1,000 people):
- fast or irregular heartbeats (also called palpitations);
- extra heartbeats;
- faster heartbeat;
- fall in blood pressure on standing-up which causes dizziness;
- malaise (generally feeling unwell);
- dizziness, fall;
- flushing.

Not known (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), 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).

Other side effects
Other side effects have occurred in a very small number of people, but their exact frequency is not known:
- dizziness (vertigo)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Bulgarian Drug Agency
8 Damyan Gruev Str.,
1303 Sofia,
Tel.: +359 2 8903417
website: www.bda.bg

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

5. How to store Pretimectal

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

Do not store above 25ºC.
Do not use this medicine after the expiry date, which is stated on the blister and on the carton after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Pretimectal contains

- The active substance is trimetazidine dihydrochloride.
- The other ingredients are: calcium hydrogen phosphate dihydrate, povidone K30, colloidal anhydrous silica, magnesium stearate, xanthan gum, microcrystalline cellulose, Opadry 03B84788 pink (hypromellose E464, titanium dioxide E171, macrogol 400 and red iron oxide E172).

What Pretimectal looks like and the contents of the pack

Pretimectal 35 mg modified-release tablets are pink, round, biconvex, embossed with “35” on one side and smooth on the other.

Packs of 30 and 60 tablets.
Not all of these pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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