Package leaflet: Information for the user

Cardizidin® MR 35 mg modified-release 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 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 Cardizidin® MR is and what it is used for

This medicine is intended for use in adults in combination with other medicines for treatment of angina pectoris (chest pain induced by coronary disease).

2. What you need to know before you take Cardizidin® MR

Do not take Cardizidin® MR:
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);
- if you have Parkinson's disease: brain disorder leading to movement impairement (shaking, difficulties in moving and stiffness, faltering, unbalanced gait);
- if you have severe problems with your kidneys.

Warnings and precautions

Talk to your doctor or pharmacist before taking **Cardizidin® MR**.

This is not an agent for treating attacks of angina nor for initial treatment of unstable angina. This is not an agent for treatment of myocardial infarction.

Inform your doctor in case of anginal attack. Laboratory investigations and change of treatment may be warranted.

This medicine may induce or worsen symptoms such as shaking, stiffness, slow movements and faltering, unbalanced gait, especially in elderly; you should look out for them and tell your doctor who may make changes in your treatment.

Children and adolescents

This medicine is not recommended for use in children and adolescents under 18 years of age.

Other medicines and Cardizidin® MR

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

There have been no reports of drug interactions so far.

Cardizidin® MR with food, drink and alcohol

Cardizidin® MR may be taken with or without food and drinks.

Pregnancy and 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.

Pregnancy

There is no experience with the use of Cardizidin® MR in pregnant women and breast-feeding mothers.

Breast-feeding

Due to lack of evidence for breast milk secretion, treatment during breast-feeding is not recommended.

Driving and using machines

This medicine may make you feel dizzy or somnolent, which will have an impact on your ability for driving and using machines.

Important information about some of the ingredient of Cardizidin® MR

Inapplicable.

3. How to take Cardizidin® MR

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults:

The usual daily dose is 1 tablet twice daily during meals in the morning and in the evening.

Use in children and adolescents:

Cardizidin® MR is not recommended for use in children and adolescents under 18 years of age, since there are no adequate evidence of safety and efficacy in this group.

If you have kidney problems or you are over 75 years of age, your doctor may adjust the recommended dose.

Method of administration:
Take orally with adequate amount of fluid.

If you take more Cardizidin® MR than you should
No cases of overdose have been reported.
In case of overdose you should contact immediately your doctor or the nearest emergency room.

If you forget to take Cardizidin® MR
Do not take a double dose to make up for a forgotten dose. Take it at the time of your next regular administration.

If you stop taking Cardizidin® MR
Inapplicable.

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.

The side effects are classified according to the frequency of occurrence and are divided in:
- Very common: may affect more than 1 per 10 people;
- Common: may affect up to 1 per 10 people;
- Uncommon: may affect up to 1 per 100 people;
- Rare: may affect up to 1 per 1,000 people;
- Very rare: may affect up to 1 per 10,000 people;
- not known (cannot be estimated from the available data).

Cardizidin® MR usually is well tolerated.

Common
Dizziness, headache, abdominal pain, diarrhea, indigestion, nausea, vomiting, rash, itching, urticaria and feeling of weakness.

Rare:
Accelerated or irregular heart activity (called palpitation), extra heart beats, accelerated heart rythm, abrupt decrease of blood pressure upon standing, which causes dizziness, mild lightheadedness or fits, malaise (general indisposition), dizziness, falls, flushing.

Frequency not known
Extrapyramidal symptoms (unusual movements, including shaking and hand and finger twisting, twisting body movements, gait instability and general stiffness of hands and feet), which usually are reversible upon treatment discontinuation.

Sleep disorders (insomnia, drowsiness), constipation, serious generalised redness of the skin with blistering, swelling of the face, lips, mouth, tongue or throat, which may cause difficulties in swallowing and breathing.

Severe reduction of the white blood cells count that makes infection occurrence more likely, platelet count reduction that increases the risk of bleeding or bruising.
Liver disorders (nausea, vomiting, appetite loss, malaise, fever, itching, yellowing of the skin and eyes, light coloured faeces, dark 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 the national reporting system.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cardizidin® MR
Keep this medicine out of the sight and reach of children.
Keep in the original package at temperature below 30° C.
Do not use this medicine after the expiry date which is stated on the carton. 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 protect the environment.

6. Contents of the pack and other information
What Cardizidin® MR tablets contain
- The active substance is trimetazidine dihydrochloride.

Each tablet contains 35 mg trimetazidine dihydrochloride.
- The other ingredients (excipients) are:

Tablet core: calcium hydrogen phosphate, anhydrous, hypromellose, carbomer, povidone, silica colloidal, anhydrous, magnesium stearate, sodium stearyl fumarate.
Film coating: polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc, iron oxide red (E172).

What Cardizidin® MR looks like and contents of the pack

Cardizidin® MR are pink, film-coated, round, biconvex modified release tablets.
The package contains 30 tablets in a PVC/AL blister.
2 blisters x 30 tablets with a leaflet in a pliable carton.

Marketing Authorisation Holder and Manufacturer:
ADIPHARM EAD
130, Simeonovsko shosse Blvd.
Sofia 1700, Bulgaria

This leaflet was last revised in:
June 2022