

Package leaflet: Information for the patient

ETACIZIN 50 mg coated tablets

Aethacizinum

Read all of this leaflet carefully before you start using 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

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1. What Etacizin is and what it is used for

The active substance of the medicine Etacizin 50 mg coated tablets *Aethacizinum* is an antiarrhythmic agent that is used for the treatment of heart rhythm disorders.

Therapeutic indications include supraventricular extrasystole, ventricular extrasystole; supraventricular tachycardia, ventricular tachycardia, atrial flutter and fibrillation.

2. What you need to know before you take Etacizin

Do not take Etacizin:

- if you are allergic to Etacizin or any of the other ingredients of this medicine (listed in section 6.);
- if you have serious structural heart disorder:
acute coronary syndrome
acute myocardial infarction and three months after acute myocardial infarction
expressed left ventricular hypertrophy
expressed heart cavity dilation
- if you have significant disorders of heart functions:

serious cardiac insufficiency (Class III and IV according to NYHA)
decreased left ventricular ejection fraction (echocardiography data)

- expressed disturbances of heart rhythm:
class II sinoatrial (SA) blockade or other *sinus arrest* cases
class II and III atrioventricular (AV) block
intraventricular conduction disorders (complete block of bundle of His)
- hard liver and/or kidney functions disorders
- breast-feeding
- children and adolescents (younger than 18 years).

Concomitant use of Etacizin and antiarrhythmic preparations such as quinidine, procainamide, disopyramide, ajmaline and monoaminooxidase (MAO) inhibitors is contraindicated.

Warnings and precautions

To achieve maximum effect with little risk, initiating therapy and periodically during therapy, your doctor may consider performing cardiological examinations.

Treatment of arrhythmia caused by myocardial infarction with Etacizin can be started with caution not earlier than 3 months after myocardial infarction.

Etacizin should be used very cautiously in case of sinus node weakness syndrome, Class I AV blockade, incomplete block of bundle of His, severe blood circulation disorders, closed-angle glaucoma, hypertrophy of benign prostate (dose should be reduced).

Etacizin may have proarrhythmic (causing arrhythmia) effect. To avoid it the following terms should be taken into account:

- 1) contraindications of administration should be strictly observed
- 2) hypokalemia should be found and prevented in time
- 3) the treatment course is advisable to start in hospital. After the first and repeated doses of the drug on the 3rd-5th days of administration it is necessary to make electrocardiogram (ECG) control or cardiac activity monitoring.

Patients with liver diseases should be careful as Etacizin can have a toxic effect on liver cells.

Other medicines and Etacizin

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

Administration of Etacizin concomitantly with antiarrhythmic preparations like quinidine, procainamide, disopyramide, ajmaline and with MAO-inhibitors is contraindicated.

β -adrenoblockers increase antiarrhythmic effect, especially in cases of arrhythmia provoked by physical load or stress. Such combination allows decreasing doses of Etacizin thus reducing frequency of adverse effects. This concomitant administration is advisable in the treatment and for prophylaxis of paroxysmal tachycardia.

Administration of Etacizin concomitantly with Digoxin increases anti-arrhythmic effect of preparations and improves the contractility of myocardium. The concomitant use of these preparations can provoke nausea and decrease appetite that is associated with increasing of Digoxin concentration in the blood. In such cases it is necessary to decrease Digoxin dose.

Etacizin with food, drink and alcohol

Alcoholic beverages should be avoided during the therapy.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

When the drug is used in women during pregnancy, it is necessary to take into account with caution the consequences of cardiac disease's non-treatment for mother and possible risk for a new-born.

Etacizin penetrates into breast milk, therefore the preparation must not be used in breast-feeding women.

Driving and using machines

Preparation use may cause dizziness, vision disturbances. In these cases it is necessary to avoid driving and operate any tools or machines.

Important information about some of the ingredients of Etacizin

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

Colouring agent Sunset Yellow in the content of tablets coating can cause allergic reactions.

3. How to take Etacizin

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

It is recommended to take tablets swallowed whole with a sufficient amount of water, independent on meals. The doctor indicates the dose and duration of treatment. The dose can be changed only according to doctor's indication.

Adults. Usually the dose is 50 mg (one tablet) two-three times daily. In case of insufficient clinical effect, the dose can be increased to 50 mg four times daily. The course of treatment depends on arrhythmia's kind, therapy efficacy and tolerability of the medicine.

Combined therapy of etacizin and β -adrenoblockers is necessary to achieve the stable antiarrhythmic effect in individual patients.

Elderly. The elderly should use the medicine with caution, it is necessary to decrease the starting dose and cautiously increase the dose.

Children and adolescents (younger than 18 years). Etacizin administration is contraindicated as there are no sufficient data on administration safety and efficacy.

Patients with hepatic failure. Patients with liver disorders should use etacizin for long-term therapy with caution as the hepatotoxic effect is possible (in case of hard disorders of liver activity administration is contraindicated).

If you feel that the effect of Etacizin is too weak or too strong, please consult your doctor.

If you take more Etacizin than you should

If you (or someone else) take too many Etacizin tablets, immediately call for medical emergency aid.

If you forget to take Etacizin

Do not take a double dose to make up for a forgotten dose.

If you stop taking Etacizin

If you have any questions about medicine use, talk to your doctor first.

4. Possible side effects

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

Using Etacizin undesirable effects may occur, especially when the high doses of the drug are used.

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

Dizziness, accommodation disorders (in the beginning of treatment), balance disorders.

Rare (may affect up to 1 in 1,000 people):

AV blockade, intraventricular conduction disorders, worsening of myocardial contractility, weakening of blood circulation that feeds heart muscle, changes in ECG, headache, nausea, pain in epigastria.

If you get any side effects not listed in this leaflet, or if any of the side effects gets serious, please tell your doctor.

5. How to store Etacizin

Do not store above 25 °C. Store in the original package in order to protect from light and moisture.

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

Do not use this medicine after the expiry date which is stated on the blister and carton pack. 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 Etacizin contains

The active substance is Etacizin (Aethacizinum) 50 mg.

The other ingredients are:

Tablet core: potato starch, sucrose, methylcellulose, calcium stearate.

Tablet coating: sucrose, povidone, calcium carbonate, magnesium carbonate light, silica, carnauba wax, colouring agents: Quinoline Yellow (E 104), Sunset Yellow (E110), titanium dioxide (E171).

What Etacizin looks like and contents of the pack

Round, biconvex tablets with yellow coating. Coating and core of almost white colour are seen in a tablet section.

10 tablets in blister; 1, 2, 3 or 5 blisters (10, 20, 30 or 50 tablets) with patient's leaflet in the carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Company name: Joint-Stock Company Olainfarm
Address: 5, Rupnicu Street, Olaine, LV-2114
Country: Latvia

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