PACKAGE LEAFLET:
Information for the patient

AMIODARON

Tablets - 200 mg
(Amiodarone Hydrochloride)

Read 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 only. 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 worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. WHAT AMIODARON IS AND WHAT IT IS USED FOR

Amiodarone is a class III antiarrhythmic; however it has several properties of the antiarrhythmics of class I, II and IV. It blocks the rapid deactivated sodium channels, as well as the potassium and calcium channels. Amiodarone non – competitively antagonizes the effects of alpha and beta adrenergic receptors. Amiodarone has an effect on heart's specific conductance system and as such it has a distinguished and safe effect on cardiac rhythm disorders.

Amiodaron is indicated in:
- fibrillation and atrial flutter, when other medicines cannot be used;
- all types of paroxysmal arrhythmias including supraventricular, nodal and ventricular tachycardias, ventricular fibrillation, when other medicines cannot be used (treatment should be started in hospital or under careful medical supervision);
- tachyarrhythmias associated with Wolff - Parkinson - White syndrome.

Your doctor may have prescribed Amiodaron for other reasons. Ask your doctor if you want to know why you are prescribed Amiodaron.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMIODARON

Do not take Amiodaron:
- if you are allergic to amiodarone hydrochloride, iodine, or to any of the ingredients of this medicine;
- if you have sinus bradycardia;
- if you have sino - atrial heart block;
- if you have atrioventricular block or other severe conduction disorders (unless the patient has a pacemaker);
- if you have thyroid dysfunction;
- if you are pregnant or breastfeeding.

If you think you have any of the above mentioned conditions, first ask your doctor and follow the given advices.

Take special care with Amiodaron
- Amiodarone should be taken upon doctor's recommendation and treatment should be monitored by a specialised doctor with knowledge and experience in the treatment of arrhythmias.
- Liver - function and thyroid - function tests are required before treatment and then every 6 months (amiodarone interferes with thyroid function tests).
- Caution is advised in sick sinus syndrome, and in combinations with digoxin, oral anticoagulants, beta – blockers and calcium - channel blockers.
- Caution is advised in the treatment of elderly patients and children, patients with heart failure, patients with liver disease, patients with hypokalemia (measure serum - potassium concentration before treatment), patients with hypotension, patients with respiratory failure and patients with porphyria and during anesthesia.
- An electrocardiogram should be performed every three months.
- Examination of chest and pulmonary function are advised before treatment and every 6 months of treatment. These examinations are obligatory if any signs of pulmonary disease appear.
- Ophthalmological examination, monitoring and treatment of changes in the eye are recommended whenever subjective disorders appear. Such examinations should be performed annually.
- Exposure to sunlight should be avoided during treatment with amiodarone. Patients should cover body's exposed parts with a sun protective cream during summer.
- Exert extreme caution or avoid use of drugs that prolong QT interval.
- Amiodarone may affect psychophysical ability to drive or use machinery.
- Patients who need medicine combinations (sofosbuvir + ledipasvir) or (sofosbuvir + daclatasvir) used in hepatitits C, should not also be given amiodarone unless there is no suitable alternative. If one of these medicine combinations is used concomitantly with amiodarone, then patients' heart function must be carefully monitored by the doctor. This may include monitoring in hospital for 48 hours after starting treatment.
- Because amiodarone remains in the body for a long time, monitoring is also needed when treatment with (sofosbuvir + ledipasvir) or (sofosbuvir + daclatasvir) is given to patients who stopped amiodarone treatment within the last few months.
- If you are taking (sofosbuvir + ledipasvir) or (sofosbuvir + daclatasvir) at the same time as amiodarone, with or without other heart medicines, and are experiencing symptoms such as slow heart beat, dizziness, faintness, unusual tiredness, shortness of breath or chest pain during treatment, contact your doctor immediately.

Other medicines and Amiodaron

Amiodarone may have a prolonged effect; drug interactions may occur for several months after treatment with it has been stopped.
- Amiodarone's concomitant use with disopyramide, flecainide, quinidine or procainamide has an additive effect and increases the risk of ventricular arrhythmia. Thus, the doses of these drugs should be decreased depending upon their plasma concentrations (quinidine dose to be decreased by 1/3 up to 1/2, procainamide dose to be decreased by 1/3).
- Amiodarone's concomitant use with sotalol or bepridil is not recommended due to increased risk of arrhythmia.
- Amiodarone's concomitant use with calcium - channel blockers (diltiazem, verapamil) or beta - blockers may increase the risk of bradycardia and atrioventricular block.
- Amiodarone's combination with tricyclic antidepressants or phenothiazines, increases the risk of ventricular arrhythmias, particularly torsades de pointes arrhythmias.
- If amiodarone is concomitantly used with warfarin, digoxin, phenytoin or cyclosporin, it is necessary to monitor these drugs' plasma concentrations and their doses should be decreased (warfarin dose to be decreased by 1/3 up to 1/2, digoxin dose to be decreased by 1/2).
- Combination of amiodarone with potassium wasting diuretics, corticosteroids or amphotericin B (intravenous administration) could cause hypokalemia, which may prolong QT interval and increase the risk of ventricular arrhythmia, including torsades de pointes arrhythmias.
- When used with cimetidine, amiodarone's plasma concentrations increase due to its decreased metabolism.
- Amiodarone's concomitant use with stimulant laxatives is not recommended due to an increased risk for ventricular arrhythmia.
- Amiodarone affects the results of thyroid function tests.
- HIV - protease inhibitors may increase amiodarone's plasma concentration.
- There is evidence that concomitant use of amiodarone with medicine combinations (sofosbuvir + ledipasvir) or (sofosbuvir + daclatasvir) increases the risk of bradycardia or heart block.

Inform your doctor or pharmacist if you are taking the above - mentioned medicines concomitantly with Amiodaron.

Taking Amiodaron with food and drinks

No data available.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or are planning a pregnancy.
Amiodarone and its major metabolite cross the placenta, thus there is a risk of pharmacologic effects on the foetus (neonatal goitre, cardiodepressor effects). Amiodarone **should not be used** during pregnancy, except when there is a vital indication for the mother.

Breast-feeding

Inform your doctor or pharmacist if you are breast-feeding.
Significant amounts of amiodarone are distributed into breast milk, therefore it **should not be used** during breast-feeding.

Driving and using machines

Amiodarone may affect psychophysical ability to drive or use machinery. Also, it may cause visual disturbances in some patients. Be careful when driving or using machinery until you know how Amiodaron affects you.

3.HOW TO TAKE AMIODARON

Always take this medicine exactly as your doctor has told you. If you feel that the effect of Amiodaron is too strong or too weak, talk to your doctor or pharmacist.
Your doctor may prescribe Amiodaron for a longer time. Ask your doctor if you are not sure for how long you should take this medicine.

Tablets should be swallowed with a glass of water.
Dosage regimen of Amiodaron is as follows:
Daily dose 1 tablet = 200 mg
- First week of treatment: 1 tablet 3 times daily.
- Second week of treatment: 1 tablet twice daily.
- From the third week of treatment (maintenance dose): 1 tablet or less once daily according to response (if necessary, 1 tablet twice daily).
- No treatment on weekends: 1 tablet daily for 5 days, then 2 days without treatment.

If you take more Amiodaron than you should

If you take more Amiodaron than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on the actions that should be taken.
Symptoms:
In general, overdosage of amiodarone may be expected to produce effects such as sinus bradycardia and/or heart block, hypotension, and QT prolongation. Nausea is likely to occur with ingestions of doses greater than 1 g.
Treatment:
Management of amiodarone overdosage generally involves symptomatic and supportive care, with ECG and blood pressure monitoring.

If you forget to take Amiodaron

If you forget to take one or more doses, take the next dose at the next prescribed time. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects. Sometimes they may be serious and sometimes not. Do not be alarmed by this list of possible side effects. You may not experience any of them.
Talk to your doctor if you experience any of these side effects:
- bradycardia and conduction disturbances, because amiodarone decreases heart rate (if pulse is less than 55/min., treatment should be temporarily discontinued);
- onset or worsening of arrhythmia;
- heart failure or aggravation of existing heart failure (in such cases treatment with cardiotonic drugs is necessary);
- gastrointestinal disorders: nausea, vomiting, constipation, metallic taste and anorexia;
- rarely, transient liver impairment (increased liver enzymes) may occur; hepatocellular necrosis may occur occasionally; in such cases liver function monitoring is necessary, particularly in patients with liver impairment history;
- reversible corneal microdeposits, vision disturbances caused by optic neuritis, neuropathy and peripheral miopathy (usually reversible on withdrawal);
- phototoxicity and persistent skin discoloration;
- hypothyroidism, hyperthyroidism;
- diffuse pulmonary and fibrotic alveolitis;
- rarely, tremor, anxiety, vertigo, headache, insomnia, fatigue, benign increase of intraocular pressure, epididymitis, ataxia, exanthema (including exfoliative dermatitis), vasculitis, thrombocytopenia and increased prothrombin time;
- benign intracranial hypertension, haemolytic or aplastic anemia.

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE AMIODARON

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 packaging.
Do not store above 25°C!

6. OTHER INFORMATION

What Amiodaron contains

The active substance is Amiodarone hydrochloride.
Each tablet contains 200 mg amiodarone hydrochloride.
The excipients are: maize starch, microcrystalline cellulose, gelatin, talc, sodium starch glycolate, magnesium stearate.

Content of the pack

Carton box with 30 tablets.

Explanatory of the illustration icons on the packaging:


Ask your doctor or pharmacist.


Should not be used during pregnancy.


Content.


Warning.


Tablet shape.

Marketing Authorisation Holder and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - Albania

This leaflet was last revised in September 2015.

SPECIFICATION

CROPING AREA 15 X 25 cm

PAY ATENTION, all the layers are visible. If you have to print this document please check or uncheck the specific layers.