Amiodarona LPH® 200 mg tablets
Amiodarone hydrochloride

Please read this entire leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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 effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Amiodarona LPH® 200 mg is and what it is used for
2. Before you take or use Amiodarona LPH® 200 mg
3. How to take or use Amiodarona LPH® 200 mg
4. Possible side effects
5. How to store Amiodarona LPH® 200 mg
6. Further information

1. What Amiodarona LPH® 200 mg is and what it is used for

Amiodarona LPH® 200 mg contains amiodarone hydrochloride, an active substance with antiarrhythmic properties. It is recommended for prevention and treatment of certain heart rhythm disorders.

2. Before you take Amiodarona LPH® 200 mg

Do not take Amiodarona LPH® 200 mg if:
- you are allergic (hypersensitive) to amiodarone, or to any of the other medicinal product;
- you are allergic (hypersensitive) to iodine;
- you suffer of certain heart rhythm disorders and/or cardiac conduction disturbances (sick sinus syndrome with marked sinus bradycardia and sino-atrial block without pacemaker (cardiac stimulator), high degree atrioventricular block without pacemaker, bifascicular or trifascicular block, episodes of bradycardia which cause syncope);
- you suffer from hyperthyroidism;
- you have very low blood pressure;
- you are pregnant, or have recently taken any other medicines, even those without medical prescription.

Using other medicines
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those without medical prescription. Your doctor will decide whether it is safe to use Amiodarona LPH® 200 mg with other drugs.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine. It is recommended avoiding the use of Amiodarona LPH® 200 mg in the first trimester of pregnancy. It is contraindicated administration of Amiodarona LPH® 200 mg in the second or the third trimester of pregnancy, and during lactation.

Driving and use of machines
During the treatment with amiodarone, may occur (especially to the beginning) drowsiness, fatigue, vertigo, which may affect the ability to drive or operate machinery.

Important information about some of the ingredients of Amiodarona LPH® 200 mg
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Amiodarona LPH® 200 mg

Please take Amiodarona LPH® 200 mg exactly your doctor told you. If you are still not sure, ask your doctor or pharmacist.

Adults
The starting dose is 600 mg (3 tablets) amiodarone hydrochloride daily for 8–10 days. In some cases and under strict medical supervision (which may include making the electrocardiogram), your doctor may increase your dose to 800–1000 mg (4–5 tablets) of amiodarone hydrochloride daily. Maintenance dose is 1–2 tablets daily for 5 days per week (with inconsecutively 2 days of rest).

Elderly
Your doctor may prescribe you a lower dose than usual. Use the tablets with a sufficient quantity of water. Do not take more tablets than your doctor recommendation.

You should avoid exposure to sunlight.

Please take Amiodarona LPH® 200 mg with food and drinks
Grapefruit juice can increase the concentration of amiodarone in blood. You should avoid grapefruit juice consumption during treatment with Amiodarona LPH® 200 mg.

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If you have taken too many tablets of Amiodarona LPH® 200 mg
Contact your doctor immediately or ask to your nearest hospital if you have taken a higher dose than you should, even you feel good, to establish the proper treatment.

If you forget to take Amiodarona LPH® 200 mg
If you have forgot to take a dose, take it as soon as you remember it. If it is nearly the time for the next dose, skip the missed dose. Do not take a double dose together to make up a forgotten tablet.

If you stop taking Amiodarona LPH® 200 mg
Do not stop the treatment and do not lower the dose without a doctor’s recommendation, even if you feel an improvement of symptoms. If you stop the treatment without a doctor’s recommendation, your condition may worsen. Ask your doctor or pharmacist if you have any further questions on the use of this product.

4. Possible side-effects
Like all medicines, Amiodarona LPH® 200 mg may cause some unwanted side effects, although not everybody gets them:
• Eye disorders: blurred vision, decreased visual acuity, sensitivity to light, dry eyes, perception of colored halo;
• Skin tissue disorders: increased sensitivity to sunlight, blue-gray colored areas of exposed skin (during long-term treatment), rash (transitory), hair loss and exfoliative dermatitis;
• Respiratory disorders: persistent cough, shortness of breath and / or fever (these may be signs of inflammation or pulmonary fibrosis);
• Hepato-biliary disorders: liver damage with jaundice (yellow skin and eyes), chronic hepatitis (in cases of prolonged treatment);
• Nervous system disorders: numbness, pins and needle sensation, pain and muscular weakness, tremors, walking and movement disorders, nightmares, sleep disturbances, headache, vertigo;
• Thyroid disorders: hyperthyroidism when may appear accentuated agitation and / or weight loss or hypothyroidism with increased tiredness, drowsiness and / or weight gain;
• Cardiac disorders: abnormal heart beats rhythm, heart failure, bradycardia (low pulse);
• Vascular disorders: inflammation of blood vessels;
• Gastrointestinal disorders: nausea, vomiting, altered taste, constipation, loss of appetite;
• Reproductive system disorders: impotence, painful inflammation of the testis;
• Blood disorders: thrombocytopenia (bleeding with frequent occurrence of bruise), aplastic or hemolytic anemia (fatigue, pallor).

Amiodarona LPH® 200 mg can sometimes cause side effects that you may not be aware, as well as changes in the electrocardiogram, an increase of serum liver enzymes and creatinine. If any of the side effects gets serious, or if you notice any side effects not in this leaflet please tell your doctor or pharmacist.

5. How to store Amiodarona LPH® 200 mg
Keep out of the reach and sight of children. Do not use Amiodarona LPH® 200 mg after the expiry date which is stated on the box or blister (after EXP). The expiry date refers to the last day of that month. Do not store at temperatures above 25°C (room temperature), store in the original package.

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 Amiodarona LPH® 200 mg contains
The active substance of Amiodarona LPH® 200 mg is amiodarone hydrochloride. The other ingredients are: lactose monohydrate, maize starch, polyvidone K 30, anhydrous colloidal silicon dioxide, talcum, magnesium stearate.

What Amiodarona LPH® 200 mg looks like and contents of the pack
Biconvex, white, uncovered tablets, with a diameter of 9 mm, having engraved on one side “A” and “200”, separated by a median line.

Contents of container
Cardboard printed box containing 2 PVC/Al blisters of 10 tablets each.
Cardboard printed box containing 3 PVC/Al blisters of 10 tablets each.
Cardboard printed box containing 100 PVC/Al blisters of 10 tablets each.

Marketing authorization holder
Labormed Pharma SA
44B, Theodor Pallady Blvd., Sector 3, Bucharest, Romania

Marketing authorization manufacturer
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This leaflet has been approved in June 2010

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