EURYTHMIC TABLET 200 MG

Amiodarone 200 mg

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What EURYTHMIC is used for

EURYTHMIC is used in:

- Treatment of uneven heartbeats where other medicines either have not worked or cannot be used.
- Treatment of an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast.
- Treatment of fast or uneven heartbeats known as atrial flutter or atrial fibrillation.
- Treatment of fast heartbeats which may happen suddenly and may be uneven.

How EURYTHMIC works

It works by controlling the uneven beating of your heart (called arrhythmias). Taking the tablets helps your heartbeat to return to normal.

Before you use EURYTHMIC

- When you must not use it

Do not use:

- If you have had an allergic hypersensitivity reaction to amiodarone or any of the ingredients of EURYTHMIC.
- If you have certain heart problems including those that may cause you to faint.
- If you have a pacemaker, your doctor may allow you to use your medicine.
- If you have or have had any thyroid problems or shock.

 If you are taking other medicine tell your doctor before starting amiodarone.

Do not take this medicine after the expiry date printed on the pack.

- Pregnancy and lactation

Do not take EURYTHMIC if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take EURYTHMIC if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Amiodarone contains iodine. Tell the doctor, if you are allergic to iodine or if you are going for some thyroid function test, as the results may be altered.

Tell your doctor; if you have allergies to any medicines and any medical conditions especially the blood pressure problems, liver problems and breathing or lung problems. If you have not told your doctor about any of the above, tell him before you start taking EURYTHMIC.

- Taking other medicines

Tell your doctor if you are taking one or more of the following medication:

- Other antiarrhythmic agents
- Beta-blockers (for high blood pressure, heart failure or migraine prevention)
- Calcium channel blockers verapamil and diltiazem (for high blood pressure or angina)
- Stimulating laxatives (for constipation)
- Diuretics (for hypertension)
- Corticosteroids (anti-inflammatory agents for arthritis, asthma or allergic conditions)
- Oral anticoagulant agents (blood thinners)
- Digoxin (for heart failure)

- Phenytoin (for fits)
- Cyclosporine (for autoimmune diseases)

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines when combined with amiodarone may cause heart problems. Other medicines and amiodarone may interfere with each other.

Please refer to your doctor or pharmacist for a more complete and detail list of medicines which might interfere with amiodarone when taken together.

How to use EURYTHMIC

- How much to use

Initial Stabilization: Usual dosage is 600 mg daily and may be continued for 8-10 days.

Maintenance: The minimum effective dosage should be used according to individual response; it may range between 100-400 mg daily. EURYTHMIC may be given on alternate days (200 mg may be given every other day).

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Take it at about the same time each day, especially in relation to mealtimes. Taking your medicine at the same time each day will have the best effect. It will also help you to remember. Use as directed by your doctor or pharmacist.

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- How long to use it

Continue taking EURYTHMIC for as long as your doctor recommends. If you stop taking this medicine the uneven heartbeats may come back. This could be dangerous.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (Overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many tablets may cause slow or rapid heartbeats.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking EURYTHMIC. Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. This medicine is not habit- forming, but stopping it suddenly may mean that your condition is no longer controlled. Do not give EURYTHMIC to anyone else, even if they have the same symptoms or condition as you. Do not take any new medicines without consulting your doctor.

- Things to be careful of

This medicine may affect your ability to drive or use machines. If blurred vision occurs, do not drive or use machines and contact your doctor immediately.

Amiodarone contains iodine. If you are going for some thyroid function test, remember to tell your doctor that you are taking amiodarone as the results may be altered.

Side effects

Like all medicines, EURYTHMIC can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the following side effects after taking this medicine:

- Thyroid problem high or low thyroid hormone levels may happen. Symptoms of low thyroid hormone levels include weight gain, reduced activity, and excessive slow heart rate with regard to the expected effect of amiodarone. Weight loss, emergence of fast heart rate, chest pain, congestive heart failure in high thyroid hormone levels.
- Visual disturbances such as foggy vision, coloured halos, blurred or decreased vision.
- Photosensitisation (sensitivity of skin to UV rays)
- Slate grey or bluish pigmentation of the skin
- Breathing difficulties
- Bradycardia (slow heart beat)
- Nausea and/or vomiting.

Other side effects not given above may also occur in some patients. Consult your doctor / pharmacist for further information.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers Reporting).

Storage and disposal of EURYTHMIC

- Storage

Keep out of the reach and sight of children. Store below 25°C in a dry place, protected from light.

- Disposal

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.

Product description

- What it looks like

White to off white colored, round, flat, uncoated beveled edge and having break line on one side of tablet

- Ingredients
- Active ingredient Amiodarone
- Inactive ingredients Crospovidone, Lactose, Microcrystalline Cellulose, Polyvinyl Pyrrolidone (k 30), Isopropyl Alcohol, Colloidal Silicon Dioxide, Magnesium Stearate

- <u>MAL Number:</u> MAL10080068AZ

Manufacturer

Troikaa Pharmaceuticals Ltd. Thol - 382 728, Gujarat, India

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Product Registration Holder

Medispec (M) Sdn Bhd (137156-U) No.55&57, Lorong Sempadan 2, (Off Boundary Road), 11400 Ayer Itam, Penang, Malaysia.

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