

AMIOHEXAL 200

Amiodarone hydrochloride (200mg)

What is in this leaflet

1. What Amiohexal is used for
2. How Amiohexal works
3. Before you use Amiohexal
4. How to use Amiohexal
5. While you are using it
6. Side effects
7. Storage and Disposal of Amiohexal
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Amiohexal is used for

Amiohexal contains the active ingredient Amiodarone hydrochloride.

Amiohexal is used to control fast or irregular heartbeat.

How Amiohexal works

Amiohexal belongs to the group of medicines called antiarrhythmics. It works by lengthening the gap between one heart beat and the next, thus helping to bring the heart rate to a slower and more regular pace.

Before you use Amiohexal

- When you must not use it

Do not take Amiohexal if you:

- Have ever had allergic reaction to Amiodarone hydrochloride, the active ingredient or to any other ingredients in Amiohexal.
- Have ever had allergic reaction to iodine
- Disease of thyroid gland
- Hypokalemia (low level of potassium salt in blood)
- Sinus bradycardia (very slow heart beat)
- Have any other heart problems particularly involving regulation of heart beat. If you are using pacemaker, your doctor may allow the use of it
- Are pregnant, think you are pregnant or planning to become pregnant or are breastfeeding

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Have a history of swelling of the face, lips, tongue, throat, hands or feet
- Have any breathing problems or asthma
- Suffer from any liver problems
- Suffer from any thyroid problems
- Have any eyes problems
- Have low blood pressure
- Other heart conditions
- Are about to have an operation
- Planning to become pregnant or are pregnant or are breastfeeding
- An elderly patient

If you are not sure whether you should start taking this medicine, consult your doctor.

- Taking other medicines

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

Some medicines and Amiohexal may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Any other medicines for your heart
- Medicines for irregular heartbeat eg. quinidine and procainamide
- Any other medicines to treat high blood pressure, particularly beta-blockers (atenolol, metoprolol) and calcium channel-blockers (nifedipine, verapamil)
- Blood thinning medicines (eg. warfarin)
- Phenytoin (for epilepsy treatment)
- Digoxin (for heart failure)
- Antibiotics medicine (e.g. fluoroquinolones)
- Anti-depressants medicines e.g. doxepin, maprotiline
- Anti-psychotics, medicines used to treat mental and emotional conditions (e.g. chlorpromazine, thioridazine)
- Medicines for allergies, antihistamines (eg. terfenadine, astemizole)
- Medicines for malaria (eg. quinine, mefloquine)
- Diuretics (medicines to increase the amount of urine) and amphotericin (antifungal medicine) which may cause low potassium and magnesium level in the blood
- General anaesthetics
- Medicine to suppress the activity of your immune system (eg. ciclosporin)

- Simvastatin and other statins group (for lowering cholesterol level)
- Fentanyl (medicine used to treat pain), sildenafil (also known as Viagra), midazolam (a sedative) and ergotamine (for migraine headaches) as combination use may result in their toxicity.

Avoid drinking grapefruit juice whilst on the treatment of Amiohexal 200 tablet as it would increase the concentration of amiodarone.

This may not be a complete list of all interactions that may occur. Ask your doctor or pharmacist if amiodarone hydrochloride may interact with other medicines that you take.

- Pregnancy and breast-feeding

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. Taking amiodarone during pregnancy may cause damage to the baby. Amiohexal is not recommended during pregnancy.

Tell your doctor if you are breast feeding or about to start breast feeding. Amiohexal 200 is not recommended for mothers who are breastfeeding. Your doctor may choose another treatment for you if you wish to breastfeed.

How to use Amiohexal

Always take Amiohexal exactly according to the instructions given to you by your doctor or pharmacists.

Swallow tablets whole with sufficient amount of liquid.

- How much to use

The dose given by your doctor may differ from this leaflet.

Adults

The usual starting dose is 200mg (1 tablet) taken 3 times daily for 8 to 10 days. Your doctor will then gradually decrease your dose, depending on your response, to maintenance dose of 200mg (1 tablet) once daily.

Children and adolescents

Not recommended.

Elderly

Caution should be exercised. Please consult doctor for the dosage to be taken.

- When to use it

Take Amiohexal at the same time every day.

- How long to use it

Continue to take your medicines as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

- If you use too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

You may need urgent medical attention.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

- Always take Amiohexal exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side

effects gets serious or anything else that make you feel unwell.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Amiohexal.
- If you are about to undergo surgery, inform your doctor that you are taking Amiohexal.
- Keep all of your doctor's appointment so that your doctor could check your progress.

- Things you must not do

- Do not stop taking your medicines without consulting your doctor.
- Do not use Amiohexal after the expiry date which is stated on the blister and carton.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

- Taking Amiohexal may make your skin more sensitive to the sun and may increase tendency to tan or even causing intense redness and swelling. Always use sunscreen and wear a hat and protective clothing when you are outdoors.
- Amiohexal can cause eye disorders and blurred vision. If you are affected do not drive or operate machinery.

Side effects

All medicines can have side effects. Amiohexal may cause unwanted side effects although not everybody gets them.

Treatment with amiodarone may cause serious lung, liver and eye damage and may worsen heart problems.

Tell your doctor or pharmacist if you notice any of the following and they worry you

- Overactive thyroid. Symptoms include weight loss, restlessness, heat intolerance, tremors, sweating, swelling of the neck, rapid heart rate.
- Underactive thyroid. Symptoms include tiredness, lethargy, muscle weakness, cramps, feeling the cold, slow heart rate, dry and flaky skin, weight gain, hair loss.
- Slow heartbeat
- Nausea, vomiting and change in the way things taste
- Sensitivity to light causes sunburn and rash
- Bluish skin discolouration
- Increased liver enzymes

- Tremor, insomnia or other sleep disorders
- A feeling of "pins and needles" or numbness in the hands, legs or feet
- Muscle weakness, uncontrolled movements or poor coordination
- Small deposits on the eyeball which may impair your vision

The above list includes the more common side effects of the medicine.

Tell your doctor immediately if you notice any of the following:

- Breathing difficulty or shortness of breath
- Worsening of irregular heart beat
- Yellowing of the skin or eyes (called jaundice, a symptom of liver changes)
- Lack of coordination, affecting balance and manner of walking, limb or eye movement and speech
- Chest pain, cough and spitting up of blood
- Faintness or light headedness
- Decreased libido
- Blurring or deterioration of vision, sensitisation of eyes to light
- Hair loss
- Blood disorders such as anaemia

The above list includes rare side effects that require immediate medical attention.

If any of following happen, tell your doctor immediately or go to the nearest hospital:

- Severe allergic reaction (rash, itching, swelling of hands, face, lips or tongue)
- Breathlessness or any breathing difficulty
- Any disturbance in heartbeat such as pounding heart, very rapid or very slow heart beat or stop beating

The above list includes rare and serious side effects. You may need urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell. Other side effects not listed above may also occur in some people.

Your doctor will monitor you very carefully for side effects. This will involve blood tests to check how well your liver and thyroid are functioning. It will also involve regular chest x-rays, ECGs and eye tests. Your doctor will tell you how often you need to have these tests. This will depend on how long you are on Amiohexal 200 therapy and what dose you are on.

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 Amiohexal

- Storage

Do not store above 30°C. Store in original package to protect from heat and moisture.

Do not store Amiohexal or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach of children.

- Disposal

The expiry date of Amiohexal is printed on the carton and blister. Do not use if after expiry date.

If your doctor tell you to stop taking Amiohexal or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

Product description

- What it looks like

Amiohexal 200 tablet is a round, white color tablet with one-sided score notch.

- Ingredients

- Active ingredient

Each Amiohexal tablet contains 200mg Amiodarone hydrochloride.

- Inactive ingredients

Polyvidone, maize starch, lactose monohydrate, colloidal silica, magnesium stearate.

- Packing

Amiohexal comes in strip packs of 20, 50 and 100 tablets per box.

- MAL Number

MAL20014330ACZ

Manufacturer

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben, Germany

For:
HEXAL AG
Industriestraße 25,
83607 Holzkirchen,
Germany

Product Registration Holder

IMEKS Pharma Sdn Bhd.
No.5&9, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur.

Date of revision

6-July-2015

Serial Number

BPFK(R4/2)060715/00175