

Read the Medication Guide that comes with amiodarone HCl tablets before you start taking them and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

### **What is the most important information I should know about amiodarone HCl tablets?**

**Amiodarone HCl tablets can cause serious side effects that can lead to death including:**

- **lung damage**
- **liver damage**
- **worse heartbeat problems**
- **thyroid problems**

Call your doctor or get medical help right away if you have any symptoms such as the following:

- shortness of breath, wheezing, or any other trouble breathing; coughing, chest pain, or spitting up of blood
- nausea or vomiting; passing brown or dark-colored urine; feel more tired than usual; your skin and whites of your eyes get yellow; or have stomach pain
- heart pounding, skipping a beat, beating very fast or very slowly; feel lightheaded or faint
- weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in your menses, swelling of your neck (goiter), nervousness, irritability, restlessness, decreased concentration, depression in the elderly, or tremor

**Because of these possible side effects, amiodarone HCl tablets should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias, for which other treatments did not**

**work or were not tolerated.**

Amiodarone HCl tablets can cause other serious side effects. See **“What are the possible or reasonably likely side effects of Amiodarone HCl tablets?”** for more information.

If you get serious side effects during treatment with amiodarone HCl tablets you may need to stop amiodarone HCl tablets, have your dose changed, or get medical treatment. Talk with your doctor before you stop taking amiodarone HCl tablets.

**You may still have side effects after stopping amiodarone HCl tablets because the medicine stays in your body months after treatment is stopped.**

Tell all your healthcare providers that you take or took amiodarone HCl tablets. This information is very important for other medical treatments or surgeries you may have.

### **What are amiodarone HCl tablets?**

Amiodarone HCl is a medicine used in adults to treat life-threatening heartbeat problems called ventricular arrhythmias, for which other treatment did not work or was not tolerated. Amiodarone HCl tablets have not been shown to help people with life-threatening heartbeat problems live longer. Treatment with amiodarone HCl tablets should be started in a hospital to monitor your condition. You should have regular check-ups, blood tests, chest x-rays, and eye exams before and during treatment with amiodarone HCl tablets to check for serious side effects.

Amiodarone HCl tablets have not been studied in children.

### **Who should not take amiodarone HCl tablets?**

**Do not take amiodarone HCl tablets if you:**

- **have certain heart conditions** (heart block, very slow heart rate, or slow heart rate with dizziness or lightheadedness)
- **have an allergy to amiodarone, iodine, or any of the other ingredients in amiodarone HCl tablets.** See the end of this Medication Guide for a complete **list of ingredients in amiodarone HCl tablets.**

**What should I tell my doctor before starting amiodarone HCl tablets?**

**Tell your doctor about all of your medical conditions including if you:**

- **have lung or breathing problems**

- **have liver problems**
- **have or had thyroid problems**
- **have blood pressure problems**
- **are pregnant or planning to become pregnant.**

Amiodarone HCl can harm your unborn baby. Amiodarone HCl can stay in your body for months after treatment is stopped. Therefore, talk with your doctor before you plan to get pregnant.

- **are breastfeeding.** Amiodarone HCl passes into your milk and can harm your baby. You should not breastfeed while taking amiodarone HCl. Also, amiodarone HCl can stay in your body for months after treatment is stopped.

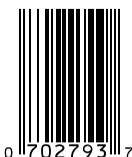
**Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements.** Amiodarone HCl tablets and certain other medicines can interact with each other causing serious side effects. Sometimes the dose of amiodarone HCl tablets or other medicines must be changed when they are used together. Especially, tell your doctor if you are taking:

- antibiotic medicines used to treat infections
- depression medicines
- blood thinner medicines
- HIV or AIDS medicines
- cimetidine (Tagamet®), a medicine for stomach ulcers or indigestion
- loratadine (for example: Claritin®, Alavert®), a medicine for allergy symptoms
- seizure medicines
- diabetes medicines
- cyclosporine, an immunosuppressive medicine
- dextromethorphan, a cough medicine
- medicines for your heart, circulation, or blood pressure
- water pills (diuretics)
- high cholesterol or bile medicines
- narcotic pain medicines
- St. John's Wort

Know the medicines you take. Keep a list of them with you at all times and show it to your doctor and pharmacist each time you get a new medicine. Do not take any new medicines while you are taking amiodarone HCl tablets unless you have talked with your doctor.

**How should I take amiodarone HCl tablets?**

- **Take amiodarone HCl tablets exactly as prescribed by your doctor.**
- The dose of amiodarone HCl tablets you take has been



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specially chosen for you by your doctor and may change during treatment. Keep taking your medicine until your doctor tells you to stop. Do not stop taking it because you feel better. Your condition may get worse. Talk with your doctor if you have side effects.

- Your doctor will tell you to take your dose of amiodarone HCl tablets with or without meals. Make sure you take amiodarone HCl tablets the same way each time.
- **Do not drink grapefruit juice during treatment with amiodarone HCl tablets.** Grapefruit juice affects how amiodarone HCl is absorbed in the stomach.
- Taking too many amiodarone HCl tablets can be dangerous. If you take too many amiodarone HCl tablets, call your doctor or go to the nearest hospital right away. You may need medical care right away.
- If you miss a dose, do not take a double dose to make up for the dose you missed. Continue with your next regularly scheduled dose.

#### **What should I avoid while taking amiodarone HCl tablets?**

- **Do not drink grapefruit juice during treatment with amiodarone HCl tablets.** Grapefruit juice affects how amiodarone HCl is absorbed in the stomach.
- **Avoid exposing your skin to the sun or sun lamps.** Amiodarone HCl tablets can cause a photosensitive reaction. Wear sun-block cream or protective clothing when out in the sun.
- **Avoid pregnancy during treatment with amiodarone HCl tablets.** Amiodarone HCl can harm your unborn baby.
- **Do not breastfeed while taking amiodarone HCl tablets.** Amiodarone HCl passes into your milk and can harm your baby.

#### **What are the possible or reasonably likely side effects of amiodarone HCl tablets?**

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Amiodarone HCl tablets can cause serious side effects that lead to death including lung damage, liver damage, worse heartbeat problems, and thyroid problems. See “What is the most important information I should know about amiodarone HCl tablets?”**

#### **Some other serious side effects of amiodarone HCl tablets include:**

- **vision problems that may lead to permanent blindness.** You should have regular eye exams before and during treatment with amiodarone HCl tablets. Call your

doctor if you have blurred vision, see halos, or your eyes become sensitive to light.

- **nerve problems.** Amiodarone HCl tablets can cause a feeling of “pins and needles” or numbness in the hands, legs, or feet, muscle weakness, uncontrolled movements, poor coordination, and trouble walking.
- **thyroid problems.** Amiodarone HCl tablets can cause thyroid problems, including low thyroid function or overactive thyroid function. Your doctor may arrange regular blood tests to check your thyroid function during treatment with amiodarone HCl. Call your doctor if you have weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in your menses, swelling of your neck (goiter), nervousness, irritability, restlessness, decreased concentration, depression in the elderly, or tremor.
- **skin problems.** Amiodarone HCl tablets can cause your skin to be more sensitive to the sun or to turn a bluish-gray color. In most patients, skin color slowly returns to normal after stopping amiodarone HCl tablets. In some patients, skin color does not return to normal.

Other side effects of amiodarone HCl tablets include nausea, vomiting, constipation, and loss of appetite.

Call your doctor about any side effect that bothers you.

These are not all the side effects with amiodarone HCl tablets. For more information, ask your doctor or pharmacist.

#### **How should I store amiodarone HCl tablets?**

- Store amiodarone HCl tablets at room temperature. Protect from light. Keep amiodarone HCl tablets in a tightly closed container.
- Safely dispose of amiodarone HCl tablets that are out-of-date or no longer needed.
- **Keep amiodarone HCl tablets and all medicines out of the reach of children.**

#### **General information about amiodarone HCl tablets**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use amiodarone HCl tablets for a condition for which it was not prescribed. Do not share amiodarone HCl with other people, even if they have the same symptoms that you have. It may harm them.

If you have any questions or concerns about amiodarone HCl tablets, ask your doctor or healthcare provider. This Medication Guide summarizes the most important informa-

tion about amiodarone HCl tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about amiodarone HCl tablets that was written for healthcare professionals.

#### **What are the ingredients in amiodarone HCl tablets?**

**Active Ingredient:** amiodarone HCl

This Medication Guide has been approved by the U.S. Food and Drug Administration.

#### **Rx only**

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