Medication Guide
Amiodarone Hydrochloride Tablets
(a-meé-oh-da-rone)

What is the most important information I should know about Amiodarone Hydrochloride Tablets?

Amiodarone Hydrochloride Tablets can cause serious side effects that can lead to death including:

- lung problems
- liver problems
- worsening heartbeat problems
- thyroid problems

Call your doctor or get medical help right away if you have any of the following symptoms during treatment with amiodarone hydrochloride tablets:

- shortness of breath, wheezing, or any other trouble breathing; coughing, chest pain, or spitting up of blood
- nausea or vomiting, brown or dark-colored urine, feel more tired than usual, yellowing of your skin or the whites of your eyes (jaundice), or right upper stomach pain
- heart pounding, skipping a beat, beating fast or slowly, feel light-headed 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.

Amiodarone Hydrochloride Tablets should only be used in people with life-threatening heartbeat problems called ventricular arrhythmias, for which other treatments did not work or were not tolerated.

Amiodarone Hydrochloride Tablets can cause other serious side effects. See “What are the possible side effects of Amiodarone Hydrochloride Tablets?” If you get serious side effects during treatment you may need to stop Amiodarone Hydrochloride Tablets, have your dose changed, or get medical treatment. Talk with your doctor before you stop taking Amiodarone Hydrochloride Tablets.

You may still have side effects after stopping Amiodarone Hydrochloride Tablets because the medicine stays in your body months after treatment is stopped.

Tell all your healthcare providers that you take or took Amiodarone Hydrochloride Tablets.

What are Amiodarone Hydrochloride Tablets?

Amiodarone Hydrochloride Tablets are a prescription medicine used to treat life-threatening heartbeat problems called ventricular arrhythmias, for which other treatment did not work or was not tolerated. Amiodarone Hydrochloride Tablets have not been shown to help people with life-threatening heartbeat problems live longer. Treatment with Amiodarone Hydrochloride 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 Hydrochloride Tablets to check for serious side effects.

It is not known if Amiodarone Hydrochloride Tablets is safe and effective in children.

Who should not take Amiodarone Hydrochloride Tablets?

Do not take Amiodarone Hydrochloride Tablets if you:

- have a certain heart condition called heart block with or without a slow heart rate
- have a slow heart rate with dizziness or lightheadedness, and you do not have an implanted pacemaker
- are allergic to amiodarone, iodine, or any of the other ingredients in Amiodarone Hydrochloride Tablets. See the end of this Medication Guide for a complete list of ingredients in Amiodarone Hydrochloride Tablets.
What should I tell my doctor before taking Amiodarone Hydrochloride Tablets?

Before you take Amiodarone Hydrochloride 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 plan to become pregnant.** Amiodarone Hydrochloride Tablets can harm your unborn baby. Amiodarone Hydrochloride Tablets can stay in your body for months after treatment is stopped. Talk with your doctor before you plan to get pregnant.
- **are breast-feeding or plan to breast-feed.** Amiodarone Hydrochloride Tablets can pass into your breast milk and can harm your baby. Talk to your doctor about the best way to feed your baby. You should not breast-feed while taking Amiodarone Hydrochloride Tablets. Also, Amiodarone Hydrochloride Tablets can stay in your body for months after treatment is stopped.
- **Tell your doctor about all the medicines you take** including prescription and over-the-counter medicines, vitamins and herbal supplements. Amiodarone Hydrochloride Tablets and certain other medicines can interact (interact) with each other and cause serious side effects. You can ask your pharmacist for a list of medicines that interact with Amiodarone Hydrochloride Tablets.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take Amiodarone Hydrochloride Tablets?

- Take Amiodarone Hydrochloride Tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much Amiodarone Hydrochloride Tablets to take and when to take it. Amiodarone Hydrochloride Tablets can be taken with or without food. Make sure you take Amiodarone Hydrochloride Tablets the same way each time.
- If you take too much Amiodarone Hydrochloride Tablets, call your doctor or go to the nearest hospital emergency room right away.
- If you miss a dose, wait and take your next dose at your regular time. Do not take two doses at the same. Continue with your next regularly scheduled dose.

What should I avoid while taking Amiodarone Hydrochloride Tablets?

- **Do not drink grapefruit juice during treatment with Amiodarone Hydrochloride Tablets.** Grapefruit juice affects how Amiodarone Hydrochloride Tablets are absorbed in the stomach.

Avoid sunlight. Amiodarone Hydrochloride Tablets can make your skin sensitive to sun and the light from sunlamps and tanning beds. You could get severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your doctor if you get sunburn.

What are the possible side effects of Amiodarone Hydrochloride Tablets?

See “What is the most important information I should know about Amiodarone Hydrochloride Tablets?”

- **vision problems that may lead to permanent blindness.** You should have regular eye exams before and during treatment with Amiodarone Hydrochloride Tablets. Call your doctor if you have blurred vision, see halos, or your eyes become sensitive to light. Tell your doctor if you plan to have laser eye surgery.
- **nerve problems.** Amiodarone Hydrochloride 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.
- **skin problems.** Amiodarone Hydrochloride Tablets can cause your skin to be more sensitive to the sun or turn a bluish-gray color. In most people, skin color slowly returns to normal after stopping Amiodarone Hydrochloride Tablets. In some people, skin color does not return to normal.
The most common side effects of Amiodarone Hydrochloride Tablets include:

- nausea
- vomiting
- constipation
- loss of appetite.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Amiodarone Hydrochloride Tablets. For more information, ask your doctor or pharmacist.

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

**How should I store Amiodarone Hydrochloride Tablets?**

- Store Amiodarone Hydrochloride Tablets at room temperature between 20° to 25°C (68° to 77°F). Protect from light.
- Keep Amiodarone Hydrochloride Tablets in a tightly closed container, and keep Amiodarone Hydrochloride Tablets out of the light.

**Keep Amiodarone Hydrochloride Tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of Amiodarone Hydrochloride Tablets**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Amiodarone Hydrochloride Tablets for a condition for which it was not prescribed. Do not give Amiodarone Hydrochloride Tablets to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Amiodarone Hydrochloride Tablets that was written for health professionals.

For more information call 1-800-525-8747 or go to [www.us.sandoz.com](http://www.us.sandoz.com).

**What are the ingredients in Amiodarone Hydrochloride Tablets?**

**Active Ingredient:** amiodarone hydrochloride

**Inactive Ingredients:** colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone and D&C yellow No. 10 aluminum lake.

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

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