

Dispense with Medication Guide available at: <https://www.taro.com/usa-medication-guides>

MEDICATION GUIDE

Amiodarone Hydrochloride

(A-mee-OH-da-rone HYE-droe-KLOR-ide) Tablets, USP

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 of heartbeat problems

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

- trouble breathing, wheezing, shortness of breath, coughing chest pain, spitting up of blood, or fever
- 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-area pain
- heart pounding, skipping a beat, beating fast or slowly, feel light-headed, or if you faint
- vision problems, including blurred vision, see halos, or your eyes become sensitive to light. You should have regular eye exams before and during treatment with amiodarone hydrochloride tablets.

Amiodarone hydrochloride tablets should be started in a hospital so that your medical condition can be carefully monitored.

Amiodarone hydrochloride tablets should only be used to treat people who have been diagnosed with life-threatening heartbeat problems called ventricular arrhythmias, when other treatments did not work or you cannot tolerate them.

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 healthcare provider 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 for months after treatment is stopped.

You should have regular check-ups, blood tests, chest x-rays before and during treatment with amiodarone hydrochloride tablets to check for serious side effects. You should also have lung function tests before starting treatment with amiodarone hydrochloride tablets.

What are amiodarone hydrochloride tablets?

Amiodarone hydrochloride tablets are a prescription medicine used to treat people who have been diagnosed with life-threatening heartbeat problems called ventricular arrhythmias, when other treatments did not work or you cannot tolerate them.

It is not known if amiodarone hydrochloride tablets are safe and effective in children.

Who should not take amiodarone hydrochloride tablets?

Do not take amiodarone hydrochloride tablets if you:

- have a serious heart problem called cardiogenic shock
- have certain types of the 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.

Before taking amiodarone hydrochloride tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have lung or breathing problems
- have liver problems
- have or had thyroid problems
- have a slow heart rate or blood pressure problems
- have diarrhea or have had diarrhea for a long period of time
- have been told that you have low levels of potassium, magnesium, or calcium in your blood
- have an implanted pacemaker or defibrillator
- if you plan to have surgery with general anesthesia
- are pregnant or plan to become pregnant. Amiodarone hydrochloride may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with amiodarone hydrochloride tablets. Amiodarone can stay in your body for months after treatment is stopped.
- are breastfeeding or plan to breastfeed. Amiodarone can pass into your breast milk and may harm your baby. You should not breast feed while taking amiodarone hydrochloride tablets. Amiodarone can stay in your body for months after treatment is stopped. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider 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 affect with each other and cause serious side effects. You can ask your pharmacist for a list of medicines that interact with amiodarone hydrochloride tablets.

How should I take amiodarone hydrochloride tablets?

- When you are discharged from the hospital, take amiodarone hydrochloride tablets **exactly** as your doctor tells you to take it.
- Your healthcare provider will tell you how much amiodarone hydrochloride tablets to take and when to take it.
- Your healthcare provider may change your dose of amiodarone hydrochloride tablets as needed if your heart rhythm is controlled, or if you have certain side effects. Your healthcare provider should monitor you carefully when your dose of amiodarone hydrochloride tablets is being changed.
- **Take your dose of amiodarone hydrochloride tablets the same way each time, either with or without food.**
- If you take too much amiodarone hydrochloride tablets, call your healthcare provider 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?

- Avoid drinking grapefruit juice during treatment with amiodarone hydrochloride tablets. Drinking grapefruit juice with amiodarone hydrochloride tablets may increase the amount of amiodarone in your blood, and this may lead to side effects.
- Amiodarone hydrochloride tablets can make your skin sensitive to sunlight. You could get severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin to help protect you if you must be in sunlight. Talk to your healthcare if you get a sunburn. See “Skin problems” in the Medication Guide section “What are the possible side effects of amiodarone hydrochloride tablets?” below.

What are the possible side effects of amiodarone hydrochloride tablets?

Amiodarone hydrochloride tablets can cause serious side effects, including:

- See “What is the most important information I should know about amiodarone hydrochloride tablets?”
- **Nerve problems.** Amiodarone hydrochloride tablets can cause nerve problems. Call your healthcare provider if you develop symptoms of nerve problems, including: a feeling of “pins and needles” or numbness in your hands, legs, or feet, muscle weakness, uncontrolled movements, poor coordination, or trouble walking.
- **Skin problems.** Amiodarone hydrochloride tablets can cause your skin to be more sensitive to the sun or turn a bluish-gray color. People who have fair skin or people who have a lot of sun exposure may be more at risk for these skin problems. Some of the bluish-gray skin color may return to normal after stopping amiodarone hydrochloride tablets.
- **Thyroid problems.** Amiodarone hydrochloride tablets can cause you to have either decreased thyroid function (hypothyroidism), which can sometimes be severe, or an overactive thyroid (hyperthyroidism), which can be severe.
 - If you develop decreased thyroid function during treatment with amiodarone, your healthcare provider may need to reduce your dose or stop your treatment with amiodarone hydrochloride tablets, and possibly prescribe medicine to replace your thyroid hormone.
 - An overactive thyroid can cause you to produce too much thyroid hormone. You can have abnormal heartbeats even while you are receiving amiodarone. Your healthcare provider may prescribe certain medicines to treat your overactive thyroid. Call your healthcare provider if you get any abnormal heart beats during treatment with amiodarone hydrochloride tablets. This may mean that you have an overactive thyroid.
 - Your healthcare provider should do tests to check your thyroid function before you start and during treatment with amiodarone hydrochloride tablets.
 - Call your healthcare provider if you develop any of the following symptoms of a thyroid problem during treatment with amiodarone hydrochloride tablets:
 - weakness
 - weight loss or weight gain
 - heat or cold intolerance
 - hair thinning
 - sweating
 - changes in your menstrual periods
 - swelling of your neck (goiter)
 - nervousness
 - irritability
 - restlessness
 - decreased concentration
 - feeling depressed (in the elderly)
 - tremor

The most common side effects of amiodarone hydrochloride tablets include:

- lung problems
- heartbeat problems
- heart problems
- liver problems

Amiodarone hydrochloride tablets may affect fertility in males and females. It is not known if the effects are reversible. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of amiodarone hydrochloride tablets. For more information, ask your healthcare provider 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).
- Keep amiodarone hydrochloride tablets in a tightly closed container, and keep amiodarone hydrochloride tablets out of the light.

Keep amiodarone hydrochloride tablets and 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. You can ask your pharmacist or healthcare provider for information about amiodarone hydrochloride tablets that is written for health professionals.

What are the ingredients in amiodarone hydrochloride tablets?

Active Ingredient: amiodarone hydrochloride

Inactive Ingredients: colloidal silicon dioxide, corn starch, D&C yellow No. 10 lake (200 and 400 mg only), FD&C yellow No. 6 lake (200 and 300 mg only), lactose anhydrous, magnesium stearate and povidone.

Manufactured by: Taro Pharmaceutical Industries Ltd.

Haifa Bay, Israel 2624761

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**

Hawthorne, NY 10532

For more information, call 1-866-923-4914 or visit www.taro.com