



ma levels of amiodarone; therefore, grapefruit juice should not be taken during treatment with oral amiodarone. This information should be considered when changing from intravenous amiodarone to oral amiodarone (see **DOSAGE AND ADMINISTRATION**).

**Amiodarone may suppress certain CYP450 enzymes, including CYP1A2, CYP2C9, CYP2D6, and CYP3A4. This inhibition can result in unexpectedly high plasma levels of other drugs which are metabolized by those CYP450 enzymes. Reported examples of this interaction include the following:**

*Immunosuppressives:*

**Cyclosporine** (CYP3A4 substrate) administered in combination with oral amiodarone has been reported to produce persistently elevated plasma concentrations of cyclosporine resultin in elevated creatinine, despite reduction in dose of cyclosporine.

*HMG-CoA reductase inhibitors:*

Simvastatin (CYP3A4 substrate) in combination with amiodarone has been associated with reports of myopathy/rhabdomyolysis.

*Cardiovasculars:*

*Cardiac glycosides:* In patients receiving **digoxin** therapy, administration of oral amiodarone regularly results in an increase in the serum digoxin concentration that may reach toxic levels with resultant clinical toxicity. Amiodarone taken concomitantly with digoxin increases the serum digoxin concentration by 70% after one day. **On initiation of oral amiodarone, the need for digitalis therapy should be reviewed and the dose reduced by approximately 50% or discontinued.** If digitalis treatment is continued, serum levels should be closely monitored and patients observed for clinical evidence of toxicity. These precautions probably should apply to digitoxin administration as well.

*Antiarrhythmics:*

Other antiarrhythmic drugs, such as **quinidine**, **procainamide**, **disopyramide**, and **phenytoin**, have been used concurrently with oral amiodarone.

There have been case reports of increased steady-state levels of quinidine, procainamide, and phenytoin during concomitant therapy with amiodarone. Phenytoin decreases serum amiodarone levels. Amiodarone taken concomitantly with quinidine increases quinidine serum concentration by 33% after two days. Amiodarone taken concomitantly with procainamide for less than seven days increases plasma concentrations of procainamide and n-acetyl procainamide by 55% and 33%, respectively. Quinidine and procainamide doses should be reduced by one-third when either is administered with amiodarone. Plasma levels of **flecainide** have been reported to increase in the presence of oral amiodarone; because of this, the dosage of flecainide should be adjusted when these drugs are administered concomitantly. In general, any added antiarrhythmic drug should be initiated at a lower than usual dose with careful monitoring.

Combination of amiodarone with other antiarrhythmic therapy should be reserved for patients with life-threatening ventricular arrhythmias who are incompletely responsive to a single agent or incompletely responsive to amiodarone. During transfer to amiodarone the dose levels of previously administered agents should be reduced by 30 to 50% several days after the addition of amiodarone, when arrhythmia suppression should be beginning. The continued need for the other antiarrhythmic agent should be reviewed after the effects of amiodarone have been established, and discontinuation ordinarily should be attempted. If the treatment is continued, these patients should be particularly carefully monitored for adverse effects, especially conduction disturbances and exacerbation of tachyarrhythmias, as amiodarone is continued. In amiodarone-treated patients who require additional antiarrhythmic therapy, the initial dose of such agents should be approximately half of the usual recommended dose.

*Antihypertensives:*

Amiodarone should be used with caution in patients receiving **β-receptor blocking agents** (e.g., propranolol, a CYP3A4 inhibitor) or **calcium channel antagonists** (e.g., verapamil, a CYP3A4 substrate, and diltiazem, a CYP3A4 inhibitor) because of the possible potentiation of bradycardia, sinus arrest, and AV block; if necessary, amiodarone can continue to be used after insertion of a pacemaker in patients with severe bradycardia or sinus arrest.

*Anticoagulants:*

Potentiation of **warfarin**-type (CYP2C9 and CYP3A4 substrate) anticoagulant response is almost always seen in patients receiving amiodarone and can result in serious or fatal bleeding. Since the concomitant administration of warfarin with amiodarone increases the prothrombin time by 100% after 3 to 4 days, **the dose of the anticoagulant should be reduced by one-third to one-half, and prothrombin times should be monitored closely.**

**Some drugs/substances are known to accelerate the metabolism of amiodarone by stimulating the synthesis of CYP3A4 (enzyme induction). This may lead to low amiodarone serum levels and potential decrease in efficacy. Reported examples of this interaction include the following:**

*Antibiotics:*

***Rifampin*** is a potent inducer of CYP3A4. Administration of rifampin concomitantly with oral amiodarone has been shown to result in decreases in serum concentrations of amiodarone and desethylamiodarone.

*Other substances, including herbal preparations:*

**St. John's Wort** (Hypericum perforatum) induces CYP3A4. Since amiodarone is a substrate for CYP3A4, there is the potential that the use of St. John's Wort in patients receiving amiodarone could result in reduced amiodarone levels.

*Other reported interactions with amiodarone:*

**Fentanyl** (CYP3A4 substrate) in combination with amiodarone may cause hypotension, bradycardia, and decreased cardiac output.

Sinus bradycardia has been reported with oral amiodarone in combination with **lidocaine** (CYP3A4 substrate) given for local anesthesia. Seizure, associated with increased lidocaine concentrations, has been reported with concomitant administration of intravenous amiodarone.

**Dextromethorphan** is a substrate for both CYP2D6 and CYP3A4. Amiodarone inhibits CYP2D6.

**Cholestyramine** increases enterohepatic elimination of amiodarone and may reduce its serum levels and t<sub>1/2</sub>.

**Disopyramide** increases QT prolongation which could cause arrhythmia.

**Fluoroquinolones, macrolide antibiotics, and azoles** are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly. (See **WARNINGS, Worsened Arrhythmia**.)

Hemodynamic and electrophysiologic interactions have also been observed after concomitant administration with **propranolol**, **diltiazem**, and **verapamil**.

*Volatile Anesthetic Agents* (see **PRECAUTIONS, Surgery, Volatile Anesthetic Agents**).

In addition to the interactions noted above, chronic (>2 weeks) **oral** amiodarone administration impairs metabolism of phenytoin, dextromethorphan, and methotrexate.

**Electrolyte Disturbances**

Since antiarrhythmic drugs may be ineffective or may be arrhythmogenic in patients with hypokalemia, any potassium or magnesium deficiency should be corrected before instituting and during amiodarone therapy. Use caution when coadministering amiodarone with drugs which may induce hypokalemia and/or hypomagnesemia.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Amiodarone HCl was associated with a statistically significant, dose-related increase in the incidence of thyroid tumors (follicular adenoma and/or carcinoma) in rats. The incidence of thyroid tumors was greater than control even at the lowest dose level tested, i.e., 5 mg/kg/day (approximately 0.08 times the maximum recommended human maintenance dose).

Mutagenicity studies (Ames, micronucleus, and lysogenic tests) with amiodarone were negative.

In a study in which amiodarone HCl was administered to male and female rats, beginning 9 weeks prior to mating, reduced fertility was observed at a dose level of 90 mg/kg/day (approximately 1.4 times the maximum recommended human maintenance dose).

\*600 mg in a 50 kg patient (dose compared on a body surface area basis)

**Pregnancy: Pregnancy Category D**

See **WARNINGS, Neonatal Hypo- or Hyperthyroidism**.

**Labor and Delivery**

It is not known whether the use of amiodarone during labor or delivery has any immediate or delayed adverse effects. Preclinical studies in rodents have not shown any effect of amiodarone on the duration of gestation or on parturition.

**Nursing Mothers**

Amiodarone and one of its major metabolites, desethylamiodarone (DEA), are excreted in human milk, suggesting that breast-feeding could expose the nursing infant to a significant dose of the drug. Nursing offspring of lactating rats administered amiodarone have been shown to be less viable and have reduced body-weight gains. Therefore, when amiodarone therapy is indicated, the mother should be advised to discontinue nursing.

**Pediatric Use**

The safety and effectiveness of amiodarone HCl in pediatric patients have not been established.

**Geriatric Use**

Clinical studies of amiodarone tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

**ADVERSE REACTIONS**

Adverse reactions have been very common in virtually all series of patients treated with amiodarone HCl for ventricular arrhythmias with relatively large doses of drug (400 mg/day and above), occurring in about three-fourths of all patients and causing discontinuation in 7 to 18%. The most serious reactions are pulmonary toxicity, exacerbation of arrhythmia, and rare serious liver injury (see **WARNINGS**), but other adverse effects constitute important problems. They are often reversible with dose reduction or cessation of amiodarone treatment. Most of the adverse effects appear to become more frequent with continued treatment beyond six months, although rates appear to remain relatively constant beyond one year. The time and dose relationships of adverse effects are under continued study.

Neurologic problems are extremely common, occurring in 20 to 40% of patients and including malaise and fatigue, tremor and involuntary movements, poor coordination and gait, and peripheral neuropathy; they are rarely a reason to stop therapy and may respond to dose reductions or discontinuation (see **PRECAUTIONS**).

Gastrointestinal complaints, most commonly nausea, vomiting, constipation, and anorexia, occur in about 25% of patients but rarely require discontinuation of drug. These commonly occur during high-dose administration (i.e., loading dose) and usually respond to dose reduction or divided doses.

Ophthalmic abnormalities including optic neuropathy and/or optic neuritis, in some cases progressing to permanent blindness, papilledema, corneal degeneration, photosensitivity, eye discomfort, scotoma, lens opacities, and macular degeneration have been reported. (See **WARNINGS**.)

Asymptomatic corneal microdeposits are present in virtually all adult patients who have been on the drug for more than 6 months. Some patients develop eye symptoms of halos, photophobia, and dry eyes. Vision is rarely affected and drug discontinuation is rarely needed.

Dermatological adverse reactions occur in about 15% of patients, with photosensitivity being most common (about 10%). Sunscreen and protection from sun exposure may be helpful, and drug discontinuation is not usually necessary. Prolonged exposure to amiodarone occasionally results in a blue-gray pigmentation. This is slowly and occasionally incompletely reversible on discontinuation of drug but is of cosmetic importance only.

Cardiovascular adverse reactions, other than exacerbation of the arrhythmias, include the uncommon occurrence of congestive heart failure (3%) and bradycardia. Bradycardia usually responds to dosage reduction but may require a pacemaker for control. CHF rarely requires drug discontinuation. Cardiac conduction abnormalities occur infrequently and are reversible on discontinuation of drug.

The following side-effect rates are based on a retrospective study of 241 patients treated for 2 to 1,515 days (mean 441.3 days).

**The following side effects were each reported in 10 to 33% of patients:**

Gastrointestinal: Nausea and vomiting.

**The following side effects were each reported in 4 to 9% of patients:**

Dermatologic: Solar dermatitis/photosensitivity.

Neurologic: Malaise and fatigue, tremor/abnormal involuntary movements, lack of coordination, abnormal gait/ataxia, dizziness, paresthesias.

Gastrointestinal: Constipation, anorexia.

Ophthalmologic: Visual disturbances.

Hepatic: Abnormal liver-function tests.

Respiratory: Pulmonary inflammation or fibrosis.

**The following side effects were each reported in 1 to 3% of patients:**

Thyroid: Hypothyroidism, hyperthyroidism.

Neurologic: Decreased libido, insomnia, headache, sleep disturbances.

Cardiovascular: Congestive heart failure, cardiac arrhythmias, SA node dysfunction.

Gastrointestinal: Abdominal pain.

Hepatic: Nonspecific hepatic disorders.

Other: Flushing, abnormal taste and smell, edema, abnormal salivation, coagulation abnormalities.

**The following side effects were each reported in less than 1% of patients:**

Blue skin discoloration, rash, spontaneous ecchymosis, alopecia, hypotension, and cardiac conduction abnormalities.

In surveys of almost 5,000 patients treated in open U.S. studies and in published reports of treatment with amiodarone HCl, the adverse reactions most frequently requiring discontinuation of amiodarone included pulmonary infiltrates or fibrosis, paroxysmal ventricular tachycardia, congestive heart failure, and elevation of liver enzymes. Other symptoms causing discontinuations less often included visual disturbances, solar dermatitis, blue skin discoloration, hyperthyroidism, and hypothyroidism.

**Postmarketing Reports**

In postmarketing surveillance, sinus arrest, hepatitis, cholestatic hepatitis, cirrhosis, epididymitis, impotence, vasculitis, pseudotumor cerebri, syndrome of inappropriate antidiuretic hormone secretion (SIADH), thrombocytopenia, angioedema, bronchiolitis obliterans organizing pneumonia (possibly fatal), bronchospasm, possibly fatal respiratory disorders (including distress, failure, arrest, and ARDS), fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates, pleuritis, pancreatitis, toxic epidermal necrolysis (sometimes fatal), myopathy, muscle weakness, rhabdomyolysis, hemolytic anemia, aplastic anemia, pancytopenia, neutropenia, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, pruritus, hallucination, confusional state, disorientation, and delirium also have been reported in patients receiving amiodarone.

**OVERDOSAGE**

There have been cases, some fatal, of amiodarone overdose.

In addition to general supportive measures, the patient's cardiac rhythm and blood pressure should be monitored, and if bradycardia ensues, a β-adrenergic agonist or a pacemaker may be used. Hypotension with inadequate tissue perfusion should be treated with positive inotropic and/or vasopressor agents. Neither amiodarone nor its metabolite is dialyzable.

The acute oral LD<sub>50</sub> of amiodarone HCl in mice and rats is greater than 3,000 mg/kg.

**DOSAGE AND ADMINISTRATION**

BECAUSE OF THE UNIQUE PHARMACOKINETIC PROPERTIES, DIFFICULT DOSING SCHEDULE, AND SEVERITY OF THE SIDE EFFECTS IF PATIENTS ARE IMPROPERLY MONITORED, AMIODARONE SHOULD BE ADMINISTERED ONLY BY PHYSICIANS WHO ARE EXPERIENCED IN THE TREATMENT OF LIFE-THREATENING ARRHYTHMIAS WHO ARE THOROUGHLY FAMILIAR WITH THE RISKS AND BENEFITS OF AMIODARONE THERAPY, AND WHO HAVE ACCESS TO LABORATORY FACILITIES CAPABLE OF ADEQUATELY MONITORING THE EFFECTIVENESS AND SIDE EFFECTS OF TREATMENT.

In order to insure that an antiarrhythmic effect will be observed without waiting several months, loading doses are required. A uniform, optimal dosage schedule for administration of amiodarone has not been determined. Because of the food effect on absorption, amiodarone should be administered consistently with regard to meals (see **CLINICAL PHARMACOLOGY**). Individual patient titration is suggested according to the following guidelines:

*For life-threatening ventricular arrhythmias, such as ventricular fibrillation or hemodynamically unstable ventricular tachycardia:* Close monitoring of the patients is indicated during the loading phase, particularly until risk of recurrent ventricular tachycardia or fibrillation has abated. Because of the serious nature of the arrhythmia and the lack of predictable time course of effect, loading should be performed in a hospital setting. Loading doses of 800 to 1,600 mg/day are required for 1 to 3 weeks (occasionally longer) until initial therapeutic response occurs. (Administration of amiodarone HCl in divided doses with meals is suggested for total daily doses of 1,000 mg or higher, or when gastrointestinal intolerance occurs.) If side effects become excessive, the dose should be reduced. Elimination of recurrence of ventricular fibrillation and tachycardia usually occurs within 1 to 3 weeks, along with reduction in complex and total ventricular ectopic beats.

Since grapefruit juice is known to inhibit CYP3A4-mediated metabolism of oral amiodarone in the intestinal mucosa, resulting in increased plasma levels of amiodarone, grapefruit juice should not be taken during treatment with oral amiodarone (see **PRECAUTIONS, Drug Interactions**).

Upon starting amiodarone therapy, an attempt should be made to gradually discontinue prior

antiarrhythmic drugs (see section on **Drug Interactions**). When adequate arrhythmia control is achieved, or if side effects become prominent, amiodarone dose should be reduced to 600 to 800 mg/day for one month and then to the maintenance dose, usually 400 mg/day (see **CLINICAL PHARMACOLOGY- Monitoring Effectiveness**). Some patients may require larger maintenance doses, up to 600 mg/day, and some can be controlled on lower doses. Amiodarone may be administered as a single daily dose, or in patients with severe gastrointestinal intolerance, as a b.i.d. dose. In each patient, the chronic maintenance dose should be determined according to antiarrhythmic effect as assessed by symptoms, Holter recordings, and/or programmed electrical stimulation and by patient tolerance. Plasma concentrations may be helpful in evaluating nonresponsiveness or unexpectedly severe toxicity (see **CLINICAL PHARMACOLOGY**).

**The lowest effective dose should be used to prevent the occurrence of side effects. In all instances, the physician must be guided by the severity of the individual patient's arrhythmia and response to therapy.**

When dosage adjustments are necessary, the patient should be closely monitored for an extended period of time because of the long and variable half-life of amiodarone and the difficulty in predicting the time required to attain a new steady-state level of drug. Dosage suggestions are summarized below:

	Loading Dose (Daily)	Adjustment and Maintenance Dose (Daily)	
Ventricular Arrhythmias	1 to 3 weeks	~1 month	usual maintenance
	800 to 1,600 mg	600 to 800 mg	400 mg

## HOW SUPPLIED

Amiodarone HCl Tablets are available as follows:

200 mg round, flat bevel edge, scored white tablets debossed “AM” on one side and “G” on the other.

Bottles of 60	NDC-49884-458-02
Bottles of 250	NDC-49884-458-04
Bottles of 500	NDC-49884-458-05
Bottles of 1000	NDC-49884-458-10

Keep tightly closed.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from light.

Dispense in a light-resistant, tight container.

Use carton to protect contents from light.

## MEDICATION GUIDE

**Amiodarone Hydrochloride (ah-ME-o-dah-rone hi-dro-KLOR-ide) Tablets**

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**

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 light-headed or faint

**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 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 can harm your unborn baby. Amiodarone can stay in your body for months after treatment is stopped. Therefore, talk with your doctor before you plan to get pregnant.
- are breast-feeding.** Amiodarone passes into your milk and can harm your baby. You should not breast-feed while taking amiodarone. Also, amiodarone 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
- 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 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 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 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 can harm your unborn baby.
- Do not breast-feed while taking amiodarone HCl tablets.** Amiodarone passes into your milk and can harm your baby.

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

**Amiodarone HCl tablets can cause serious side effects that lead to death including lung damage, liver damage, and worse heartbeat 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 hypothyroidism or hyperthyroidism. Your doctor may arrange regular blood tests to check your thyroid function during treatment with amiodarone. Call your doctor if you have weight loss or weight gain, restlessness, weakness, heat or cold intolerance, hair thinning, sweating, changes in your menses, or swelling of your neck (goiter).
- 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 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 information 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?**