

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

Pacerone[®] (Amiodarone HCl) Tablets, 200 mg, are available in bottles of 60 tablets (NDC 0245-0147-60), bottles of 90 tablets (NDC 0245-0147-90), bottles of 500 tablets (NDC 0245-0147-15) and in unit dose cartons of 100 tablets (10 cards containing 10 tablets each) (NDC 0245-0147-01).

Pacerone[®] Tablets are pink, round, flat-faced, scored, uncoated tablets, debossed with “P₂₀₀” on the unscored side, and “U-S” above and “0147” below the score on the reverse side.

Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature.] Protect from light.

Dispense in a tight, light-resistant container with a child-resistant closure.



This Medication Guide may have been revised after this copy was produced. For more information and the most current Medication Guide, please visit www.pacerone.com or www.upsher-smith.com or call our professional services department toll-free at 1-800-654-2299.



Medication Guide

Pacerone[®] (P#S-#r-#n) Tablets (Amiodarone HCl)

Rx only

Read the Medication Guide that comes with Pacerone[®] 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 Pacerone[®] Tablets?

Pacerone[®] 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, Pacerone[®] 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.

Pacerone[®] Tablets can cause other serious side effects. See “**What are the possible or reasonably likely side effects of Pacerone[®] Tablets?**” for more information.

If you get serious side effects during treatment with Pacerone[®] Tablets you may need to stop Pacerone[®] Tablets, have your dose changed, or get medical treatment. Talk with your doctor before you stop taking Pacerone[®] Tablets.

You may still have side effects after stopping Pacerone[®] Tablets because the medicine stays in your body months after treatment is stopped.

Tell all your healthcare providers that you take or took Pacerone[®] Tablets. This information is very important for other medical treatments or surgeries you may have.

What are Pacerone[®] 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. Pacerone[®] Tablets have not been shown to help people with life-threatening heartbeat problems live longer. Treatment with Pacerone[®] 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 Pacerone[®] Tablets to check for serious side effects.

Pacerone[®] Tablets have not been studied in children.

Who should not take Pacerone[®] Tablets?

Do not take Pacerone[®] 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 Pacerone[®] Tablets.** See the end of this Medication Guide for a complete list of ingredients in Pacerone[®] Tablets.

What should I tell my doctor before starting Pacerone[®] 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 breastfeeding.** Amiodarone passes into your milk and can harm your baby. You should not breastfeed while taking Pacerone[®] Tablets. 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. Pacerone[®] Tablets and certain other medicines can interact with each other causing serious side effects. Sometimes the dose of Pacerone[®] 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 Pacerone[®] Tablets unless you have talked with your doctor.

How should I take Pacerone[®] Tablets?

- **Take Pacerone[®] Tablets exactly as prescribed by your doctor.**
- The dose of Pacerone[®] 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 Pacerone[®] Tablets with or without meals. Make sure you take Pacerone[®] Tablets the same way each time.
- **Do not drink grapefruit juice during treatment with Pacerone[®] Tablets.** Grapefruit juice affects how amiodarone is absorbed in the stomach.
- Taking too many Pacerone[®] Tablets can be dangerous. If you take too many Pacerone[®] 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 Pacerone[®] Tablets?

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

What are the possible or reasonably likely side effects of Pacerone[®] Tablets?

Pacerone[®] 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 Pacerone[®] Tablets?”

Some other serious side effects of Pacerone[®] Tablets include:

- **vision problems that may lead to permanent blindness.** You should have regular eye exams before and during treatment with Pacerone[®] Tablets. Call your doctor if you have blurred vision, see halos, or your eyes become sensitive to light.
- **nerve problems.** Pacerone[®] 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.** Pacerone[®] 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 Pacerone[®] Tablets. 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.** Pacerone[®] 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 Pacerone[®] Tablets. In some patients, skin color does not return to normal.

Other side effects of Pacerone[®] 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 Pacerone[®] Tablets. For more information, ask your doctor or pharmacist.

How should I store Pacerone[®] Tablets?

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

General information about Pacerone[®] Tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Pacerone[®] Tablets for a condition for which it was not prescribed. Do not share Pacerone[®] Tablets 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 Pacerone[®] Tablets, ask your doctor or healthcare provider. This Medication Guide summarizes the most important information about Pacerone[®] Tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Pacerone[®] Tablets that was written for healthcare professionals.



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What are the ingredients in Pacerone[®] Tablets?

Active Ingredient: amiodarone HCl, 200 mg

Inactive Ingredients: lactose monohydrate, magnesium stearate, povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid, FD&C Red 40 and FD&C Yellow 6.

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

Rx only

Manufactured by

UPSHER-SMITH LABORATORIES, INC.

Minneapolis, MN 55447

US Patent 5,785,995

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