



Pacerone® Tablets 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 hydrochloride tablets 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 mg to 1,600 mg	600 mg to 800 mg	400 mg

#### HOW SUPPLIED

Pacerone® (Amiodarone Hydrochloride) Tablets, 400 mg, are available in unit dose cartons of 100 tablets (10 cards containing 10 tablets each) (NDC 0245-0145-01). The 400 mg tablets are light yellow, oval-shaped, scored, uncoated tablets, debossed with “P400” on the unscored side, and “01” to the left and “45” to the right of the score on the reverse side.

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

**Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure as required.**

Protect from light.

KEEP TIGHTLY CLOSED.

This product’s label may have been revised after this insert was used in production. For further product information and current package insert, please visit www.upsher-smith.com or call 1-888-650-3789.

Manufactured for  
**UPSHER-SMITH LABORATORIES, INC.**  
Maple Grove, MN 55369

112032-01

Revised 1116

## Medication Guide Pacerone® (PĀS-ər-ŏn) Tablets (Amiodarone Hydrochloride)

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 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 Pacerone® 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.

**Pacerone® 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.**

Pacerone® Tablets can cause other serious side effects. See **“What are the possible side effects of Pacerone® Tablets?”** If you get serious side effects during treatment 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.

#### What are Pacerone® Tablets?

Pacerone® 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. Pacerone® Tablets have not been shown to help people with life-threatening heartbeat problems live longer. 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.

It is not known if Pacerone® Tablets is safe and effective in children.

#### Who should not take Pacerone® Tablets?

**Do not take Pacerone® 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 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 taking Pacerone® Tablets?

**Before you take 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 plan to become pregnant.** Pacerone® Tablets can harm your unborn baby. Pacerone® 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.** Pacerone® 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 Pacerone® Tablets. Also, Pacerone® 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. Pacerone® Tablets and certain other medicines can affect (interact) with each other and cause serious side effects. You can ask your pharmacist for a list of medicines that interact with Pacerone® 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 Pacerone® Tablets?

- Take Pacerone® Tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much Pacerone® Tablets to take and when to take it. Pacerone® Tablets can be taken with or without food. Make sure you take Pacerone® Tablets the same way each time.
- If you take too much Pacerone® 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 time. 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 Pacerone® Tablets are absorbed in the stomach.
- Avoid sunlight.** Pacerone® 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 Pacerone® Tablets?

See **“What is the most important information I should know about Pacerone® Tablets?”**

- 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. Tell your doctor if you plan to have laser eye surgery.
- 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.
- skin problems.** Pacerone® 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 Pacerone® Tablets. In some people, skin color does not return to normal.

The most common side effects of Pacerone® 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 Pacerone® 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 Pacerone® Tablets?

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

**Keep Pacerone® Tablets and all medicines out of the reach of children.**

#### General information about the safe and effective use of 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 give Pacerone® 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 Pacerone® Tablets that was written for health professionals.

This Medication Guide may have been revised after this copy was produced. For more information and the most current Medication Guide, please visit www.upsher-smith.com or call 1-888-650-3789.

#### What are the ingredients in Pacerone® Tablets?

**Active Ingredient:** amiodarone hydrochloride, 400 mg

**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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#### Rx only

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