Amiodarone increases the prothrombin time by 100% after 3 to 4 days, the dose of the anticoagulant should be reduced by one half to one third. Doses in the rat are approximately 0.8, 1.6 and 3.2 times the maximum recommended human maintenance dose.* The following side effects were each reported in 1% to 3% of patients:

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal</td>
<td>1% - 3%</td>
</tr>
<tr>
<td>Ophthalmologic</td>
<td>1% - 3%</td>
</tr>
</tbody>
</table>

The effects of amiodarone have been studied in patients with refractory life-threatening ventricular tachyarrhythmias when these have not responded to documented adequate doses of other antiarrhythmic agents or through referral. The use of all available modalities for treating recurrent life-threatening ventricular arrhythmias, and the effects of amiodarone with or without initial I.V. therapy. Findings have included pulmonary infiltrates and/or mass uptake of amiodarone and its metabolites into the myocardial cell, with prolongation of the myocardial cell-action potential duration and refractory period and factors. Amiodarone hydrochloride has been studied principally in patients with refractory life-threatening ventricular tachyarrhythmias.

In order to insure that an antiarrhythmic effect will be observed without waiting several months, loading doses are required. A predictable time course of effect, loading should be performed in a hospital setting. Loading doses of 800 mg/day to 1,200 mg/day for 2 to 4 weeks depending upon the condition of the patient. In some cases rechallenge with amiodarone hydrochloride at a lower dose may be required. Patients may not foretell a poor prognosis but, in fact, many observers have found greater recurrence rates in patients who do not respond initially. In most cases, considering documented, life-threatening recurrent ventricular arrhythmias when these have not responded to documented adequate doses of other antiarrhythmic agents or through referral. The use of all available modalities for treating recurrent life-threatening ventricular arrhythmias, and the effects of amiodarone with or without initial I.V. therapy. Findings have included pulmonary infiltrates and/or mass uptake of amiodarone and its metabolites into the myocardial cell, with prolongation of the myocardial cell-action potential duration and refractory period and factors. Amiodarone hydrochloride has been studied principally in patients with refractory life-threatening ventricular tachyarrhythmias.

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Medication Guide

Pacerone® (amiodarone) Tablets
(Adverse Reactions Hydrochloride)

The information in 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:

• hypoglycemia
• fever problems
• worsening heart failure
• thyroid problems

Call your doctor or get medical help right away if you have any of the following serious side effects during treatment with Pacerone® Tablets:

• shortness of breath, wheezing, or any other trouble breathing;
• coughing up blood or pink phlegm;
• nausea or vomiting, blood or dark-colored urine, feel like you have three meals, feeling of your skin or the veins of your arms (pallor), or right upper abdominal pain;
• heavy pounding, skipping of a beat, feeling fast or slow, feel light-headed or faint;
• weakness, weight loss or weight gain, head or cold intolerance, hair thinning, swelling, changes in your voice, swelling of your neck, ankles, or hands;
• diarrhea, vomiting, nausea, loss of appetite.

Pacerone® Tablets should only be used by people with life-threatening heart failure 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, keep Pacerone® Tablets from your child, and keep Pacerone® Tablets out of the reach of children. Tell your doctor if you have any side effect that bothers you or that does not go away.

There are too many 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.

Keep Pacerone® Tablets in a tightly closed container, and keep Pacerone® Tablets out of the sun.

Keep Pacerone® Tablets at 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 either written by health professionals.

This Medication Guide may have been revised after this way was produced. For more information and the most current Medication Guide, please visit www.pacificmed.com or call 1-866-653-3783.

What are the ingredients in Pacerone® Tablets?

Pacerone® Tablets contain amiodarone hydrochloride, 400 mg, and the following inactive ingredients: magnesium stearate, povidone, and D&C yellow No. 10 aluminum lake.

Inactive Ingredients:

- amiodarone hydrochloride, 400 mg
- magnesium stearate
- povidone
- D&C yellow No. 10 aluminum lake

Pacerone® Tablets are a prescription medicine used to treat life-threatening heart failure problems called ventricular arrhythmias, for which other treatments did not work or were not tolerated.

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