Wyeth

December 30, 2004

Dear Health Care Professional:

Wyeth wishes to inform you that the Food and Drug Administration (FDA) requires pharmacists and other health care professionals who dispense medication to distribute Medication Guides to patients for certain products, including Cordarone® (amiodarone HCl) Tablets. The FDA requires that a Medication Guide be distributed directly to each patient to whom Cordarone Tablets are dispensed.

The Cordarone Tablets Medication Guide should not be used as a substitute for talking to patients about the risks relative to benefits associated with taking Cordarone Tablets. You are only required to distribute the Medication Guides if you are the dispenser of the medication.

Enclosed are copies of both the Cordarone Tablets Prescribing Information and the Cordarone Tablets Medication Guide. The Cordarone Tablets Medication Guide is also available on the Wyeth product information Web site: http://www.wyeth.com. Click on "Products" and scroll down to Cordarone® (amiodarone HCl) Tablets, Patient Information.

Wyeth is committed to providing you with current product information and therefore is sending you this letter. Should you have any questions concerning Cordarone Tablets product information, please call 1-800-934-5556, or check the Wyeth product information Web site.

Please see the following important boxed Warnings about Cordarone Tablets.

In addition, you can send adverse event information directly to Wyeth Global Safety Surveillance and Epidemiology (GSSE) by fax to 610-989-5544 or by mail to GSSE, 500 Arcola Road, Collegeville, PA 19426.

Adverse event information may also be reported to the FDA MedWatch Reporting System by phone (1-800-FDA-1088), fax (1-800-FDA-0178), via the MedWatch Web site at www.fda.gov/medwatch, or by mail (using postage paid form) to MedWatch, HF-2, 5600 Fisher's Lane, Rockville, MD 20852-9787.

Wyeth

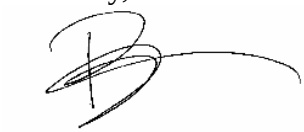
Cordarone® (amiodarone HCl) is intended for use only in patients with the indicated life-threatening arrhythmias because its use is accompanied by substantial toxicity.

Cordarone has several potentially fatal toxicities, the most important of which is pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) that has resulted in clinically manifest disease at rates as high as 10 to 17% in some series of patients with ventricular arrhythmias given doses around 400 mg/day, and as abnormal diffusion capacity without symptoms in a much higher percentage of patients. Pulmonary toxicity has been fatal about 10% of the time. Liver injury is common with Cordarone, but is usually mild and evidenced only by abnormal liver enzymes. Overt liver disease can occur, however, and has been fatal in a few cases. Like other antiarrhythmics, Cordarone can exacerbate the arrhythmia, e.g., by making the arrhythmia less well tolerated or more difficult to reverse. This has occurred in 2 to 5% of patients in various series, and significant heart block or sinus bradycardia has been seen in 2 to 5%. All of these events should be manageable in the proper clinical setting in most cases. Although the frequency of such proarrhythmic events does not appear greater with Cordarone than with many other agents used in this population, the effects are prolonged when they occur.

Even in patients at high risk of arrhythmic death, in whom the toxicity of Cordarone is an acceptable risk, Cordarone poses major management problems that could be life-threatening in a population at risk of sudden death, so that every effort should be made to utilize alternative agents first.

The difficulty of using Cordarone effectively and safely itself poses a significant risk to patients. Patients with the indicated arrhythmias must be hospitalized while the loading dose of Cordarone is given, and a response generally requires at least one week, usually two or more. Because absorption and elimination are variable, maintenance-dose selection is difficult, and it is not unusual to require dosage decrease or discontinuation of treatment. In a retrospective survey of 192 patients with ventricular tachyarrhythmias, 84 required dose reduction and 18 required at least temporary discontinuation because of adverse effects, and several series have reported 15 to 20% overall frequencies of discontinuation due to adverse reactions. The time at which a previously controlled life-threatening arrhythmia will recur after discontinuation or dose adjustment is unpredictable, ranging from weeks to months. The patient is obviously at great risk during this time and may need prolonged hospitalization. Attempts to substitute other antiarrhythmic agents when Cordarone must be stopped will be made difficult by the gradually, but unpredictably, changing amiodarone body burden. A similar problem exists when Cordarone is not effective; it still poses the risk of an interaction with whatever subsequent treatment is tried.

Sincerely,



Brenda Cooperstone, MD
Vice President, Global Medical Affairs

Enclosures: Cordarone Tablets Prescribing Information
Cordarone Tablets Medication Guide