

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20377/S001**

**ADMINISTRATIVE DOCUMENTS**

CSO Review of Draft Labeling  
NDA 20-377/S-001

OCT 18 1995

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**Sponsor:** Wyeth-Ayerst Laboratories  
**Product:** Cordarone (amiodarone HCl) I.V.  
**Submission Date:** September 19, 1995  
**Receipt Date:** September 21, 1995  
**Type of Submission:** Special Supplement - Changes Being Effected

**Background:** NDA 20-377 was approved on August 3, 1995. On September 7, 1995, Wyeth-Ayerst submitted final printed labeling. S-001 was submitted on September 19, 1995 to incorporate modifications to the **Dosage and Administration** section of the package insert.

**Evaluation:** Under **Dosage and Administration**, in the **CORDARONE I.V. DOSE RECOMMENDATIONS** chart, under "Loading Infusions", the words "Rapid" and "Slow" are now preceded by the modifiers "First" and "Followed by," respectively. The chart has been changed from:

**CORDARONE I.V. DOSE RECOMMENDATIONS  
-FIRST 24 HOURS-**

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Loading infusions	<b>Rapid:</b> 150 mg over the <b>FIRST</b> 10 minutes (15 mg/ml). Add 13 mL of Cordarone I.V. (150 mg) to 100 mL D <sub>5</sub> W (concentration = 1.5 mg/ml). Infuse 100 mL over 10 minutes.
	<b>Slow:</b> 360 mg over the <b>NEXT</b> 6 hours (1 mg/min). Add 18 mL of Cordarone I.V. (900 mg) to 500 mL D <sub>5</sub> W (concentration = 1.8 mg/mL).
Maintenance infusion	540 mg over the <b>REMAINING</b> 18 hours (0.5 mg/min). Decrease the rate of the slow loading infusion to 0.5 mg/min.

to:

**CORDARONE I.V. DOSE RECOMMENDATIONS  
-FIRST 24 HOURS-**

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Loading infusions First Rapid: 150 mg over the FIRST 10 minutes (15 mg/ml).  
Add 13 mL of Cordarone I.V. (150 mg) to 100 mL D<sub>5</sub>W  
(concentration = 1.5 mg/ml). Infuse 100 mL over 10 minutes.

Followed by Slow: 360 mg over the NEXT 6 hours (1 mg/min).  
Add 18 mL of Cordarone I.V. (900 mg) to 500 mL D<sub>5</sub>W  
(concentration = 1.8 mg/mL).

Maintenance infusion 540 mg over the REMAINING 18 hours (0.5 mg/min).  
Decrease the rate of the slow loading infusion to 0.5 mg/min.

**Comments/Recommendations:** Dr. Stockbridge, the medical officer, has no objection to these changes. An approval letter should issue for this supplement.

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Diana M. Willard  
Consumer Safety Officer

cc: original file  
HFD-110  
HFD-111/DWillard  
HFD-111/SBenton