

**IMMEDIATE ATTENTION REQUIRED
DISPENSING ERRORS ALERT**

**OMACOR[®] (omega-3-acid ethyl esters) Capsules and AMICAR[®] (aminocaproic acid) Tablets
DISPENSING ERRORS**

February 24, 2006

Dear Pharmacist:

Further to the November 2005 communication, Reliant Pharmaceuticals, Inc. has been made aware of additional instances where **telephone orders** for prescriptions of Omacor[®] (omega-3-acid ethyl esters) Capsules have been misunderstood and dispensed at the pharmacy level as Amicar[®] (aminocaproic acid) Tablets, a product of Xanodyne Pharmaceuticals, Inc. Your assistance is requested in clarifying oral and written prescriptions for these two products to help avoid dispensing errors.

Patients erroneously receiving Amicar[®] may be unnecessarily subjected to the risk of serious adverse effects (please refer to Amicar[®] prescribing information). Conversely, patients with high triglycerides who do not receive their Omacor[®] due to a dispensing error would be inadequately treated and would not receive the prescribed clinical benefit.

Omacor[®] Capsules are available as printed soft-gelatin capsules with the following characteristics:

Capsule	Color	Printing	Sample
1 g	Transparent soft-gelatin capsule filled with light-yellow oil	“OMACOR” on one side	

Amicar[®] Tablets are available as white, scored tablets with the following characteristics:

Tablet	Shape	Engraving	Sample
500 mg	Round	“A” to the left of the score and “10” on the right of the score on one side, “XP” on the other side	
1000 mg	Oblong	“A” to the left of the score and “20” on the right of the score on one side, “XP” on the other side	

If you do not wish to receive any more faxes from /alert Marketing, Inc., please call 800-311-0217 (toll free) and refer to PIN 1282 and ask to have your fax number removed from our database; or return this fax to 866-864-7095 and write “Please remove this fax number” AND the fax number you wish to have removed clearly on the fax; or visit www.donotsend.net and your fax number will be placed on our “Do Not Fax” List. Failure to comply with your request in the shortest reasonable time set by the FCC is unlawful.

Omacor[®] was recently introduced into the market after its approval by the FDA as an adjunct to diet for the reduction of very high triglyceride levels¹. Omacor[®] comes as a 1 g, transparent, gold gelatin capsule for oral administration, and it is usually prescribed for chronic therapy at the dose of 4 capsules (4 g) per day.

In contrast, Amicar[®] is approved for enhancing hemostasis when fibrinolysis contributes to bleeding². In certain individuals, Amicar[®] is prescribed for oral use to control acute or chronic bleeding syndromes. Amicar[®] comes as a 500 mg or 1000 mg (1 g) white tablet, or as a 250 mg/5 mL oral solution. The dosage of Amicar[®] can be highly variable, since it should be titrated to the lowest effective dose for bleeding control.

WHAT YOU CAN DO TO REDUCE THE POTENTIAL FOR DISPENSING ERRORS

- **Set a look-alike alert in the computer system**
- **Verify the generic name, along with the trade name, with the prescribing physician**
- **Verify verbal orders for Omacor[®] and Amicar[®] by asking the prescriber to spell the drug name and/or state the medication's indication**
- **Verify the dosage form, Omacor[®] Capsules versus Amicar[®] Tablets, with the prescriber**
- **Match the drug's indication to the patient's diagnosis before dispensing either drug**

At Reliant Pharmaceuticals, we are committed to patient safety and we wish to minimize the potential for prescribing and/or dispensing errors. Please share the enclosed information with co-workers and staff. Further, we will be working with all of our sales associates to heighten the awareness of potential prescribing and/or dispensing errors amongst physicians, pharmacists, and their staffs. In addition, we will add this information to our web site (www.omacorr.com) so that it is readily available.

Reliant is in the process of developing a “shelf talker” to help ensure appropriate dispensing of Omacor[®] Capsules and Amicar[®] Tablets. We anticipate providing it to you in the near future and encourage you to utilize the “shelf talker” to help prevent any more medication errors.

If you become aware of any medication errors involving Omacor[®] Capsules, report them immediately to Reliant at 1-877-311-7515, and if Amicar[®] Tablets are involved, also report the error to Xanodyne Pharmaceuticals at 1-513-636-5145. Medication errors should also be reported to the USP Medication Error Reporting Program in cooperation with the Institute for Safe Medication Practices (1-800-23ERROR; or 1-800-FAIL-SAF) or FDA's MedWatch Adverse Event Reporting Program (1-800-FDA-1088).

Thank you for your attention to this matter. For additional medical information about Omacor[®] Capsules, please call 1-877-311-7515 from 9AM to 5PM EST, Monday through Friday.

Sincerely,



Robert Shalwitz, MD
Vice President, Clinical Development
Reliant Pharmaceuticals, Inc.



Gerard Abate, MD
Medical Director
Reliant Pharmaceuticals, Inc.

PLEASE REFER TO COMPLETE PRESCRIBING INFORMATION FOR OMACOR[®] AT WWW.OMACORRX.COM.

1. Package Insert – Omacor[®] (omega-3-acid ethyl esters) Capsules. Reliant Pharmaceuticals, Inc. Liberty Corner, NJ 07938. REVISED SEPTEMBER 2005
2. Package Insert – Amicar[®] (aminocaproic acid) Tablets. Physicians' Desk Reference 2006