October 5, 2000

Re: Urgent Drug Recall Letter – Etodolac Capsules 300 mg

Dear Health Care Provider:

ESI Lederle is voluntarily recalling Lot number 9991052 of its Etodolac Capsules 300 mg, which is a generic version of Lodine® (etodolac capsules and tablets). Etodolac, a nonsteroidal anti-inflammatory drug, is indicated for acute and long-term use in the management of signs and symptoms of osteoarthritis and rheumatoid arthritis. It is also indicated for the management of pain.

Results from routine product stability testing of Lot number 9991052 of Etodolac Capsules found that some capsules from this lot may contain a variable and unknown quantity of acebutolol, a selective beta blocker, indicated for the treatment of hypertension and ventricular arrhythmias. A small number of capsules available for testing showed a range of acebutolol of 0.4 mg to 135.3 mg per capsule. The maximum amount of acebutolol that could be contained in a capsule of that size is 404 mg.

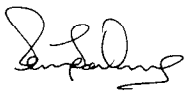
The administration of a cardioselective beta blocker such as acebutolol hydrochloride to certain patients has the potential to result in serious adverse health effects. For complete details, please refer to the enclosed acebutolol hydrochloride package insert for contraindications, warnings, precautions and adverse reactions. Patients who have previously discontinued taking etodolac from the affected lot and who have not experienced side effects should not be concerned.

The ESI Lederle 300 mg Etodolac Capsule is a white capsule marked in red with "300" on one end and "59911" over "3607" on the other end. Lot number 9991052 was manufactured in September 1999 and was shipped starting October 18, 1999 through August 31, 2000.

ESI Lederle will be notifying wholesalers, pharmacies and health care providers of this recall. Notification of the recall will be taken to the consumer level, and patients will be advised to discuss this issue with their pharmacist. Patients are also being advised to contact their health care provider should it be determined that they may be taking product from Lot number 9991052 or if they have any questions. Patients should return all affected Etodolac 300 mg capsules to ESI Lederle by calling 1-800-747-7016. The U.S. Food and Drug Administration has full knowledge of this recall.

A copy of the full Prescribing Information for both etodolac capsules and acebutolol HCl are enclosed for your reference. If you need any additional information, please contact our Product Information Department at 1-800-747-7016.

Sincerely,



Philip J. de Vane, M.D.
Vice President, Clinical Affairs
North American Medical Director

Enclosures: Etodolac Capsules full Prescribing Information
Acebutolol Hydrochloride full Prescribing Information