



King Pharmaceuticals,™ Inc.  
501 Fifth Street  
Bristol, TN 37620

800-336-7783  
423-989-8000

September 17, 2004

Dear Healthcare Professional:

Jones Pharma Incorporated™, a wholly owned subsidiary of King Pharmaceuticals®, Inc., would like to inform you about new additions to the labeling of *Levoxyl*® (levothyroxine sodium) regarding safety. Some patients have reported choking, gagging, tablet stuck in throat and dysphagia while taking *Levoxyl*®. This has been reported, predominately when *Levoxyl*® tablets were not taken with water.

In order to communicate this product information to health care professionals, the following Information for Patients section of PRECAUTIONS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION have been added to the package insert with respect to use of *Levoxyl*®.

**Information for Patients**

Levoxyl may rapidly swell and disintegrate resulting in choking, gagging, the tablet getting stuck in your throat or difficulty swallowing. It is very important that you take the tablet with a full glass of water. Most of these problems disappeared when Levoxyl tablets were taken with water.

**ADVERSE REACTIONS**

In addition to the above events, the following have been reported, predominately when Levoxyl tablets were not taken with water: choking, gagging, tablet stuck in throat and dysphagia.

**DOSAGE AND ADMINISTRATION**

Levoxyl should be taken with water (see **Information for Patients and ADVERSE REACTIONS**).

Jones Pharma Incorporated™ is committed to the safety of all patients™ receiving *Levoxyl*®. Should you have any questions or concerns regarding this important safety information, please contact Jones Pharma Product Information at 1-800-776-3637. It is important that you forward any adverse event information associated with the use of *Levoxyl*® to Jones Pharma at 1-800-546-4905. You can also report this information directly to the FDA via the MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178 ) or by the internet ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

Enclosed, for your information, is a revised copy of the package insert for *Levoxyl*®.

Sincerely,

A handwritten signature in black ink that reads "Charles Pamplin, III".

Charles Pamplin, III, MD  
Vice President, Medical Affairs