



## FORMULATION

## Water a Must for Levoxyl Users

Drug manufacturer King Pharmaceutical has issued a “dear doctor” letter advising healthcare professionals to warn patients of adverse reactions to Levoxyl, a hormone supplement used to treat hypothyroidism. Since the drug’s FDA-approved reformulation in 2001, there have been reports by Levoxyl users of reactions ranging from choking and gagging to dysphagia. According to the letter, these safety issues have been reported predominantly by patients who have swallowed Levoxyl without the assistance of water.

James Green, vice president of corporate affairs at King Pharmaceuticals, says that the new formulation of Levoxyl is a dry-compression formula in which no water is used. “Levothyroxine sodium products have had a history of problems with stability,” Green says. “[There have been problems] maintaining the appropriate level of the active

ingredient in the product over a sustained period of time, because the active ingredient tends to degrade over time. Water actually contributes to that degradation process, and so by removing water from the formulation you create a more stable [drug].” However, the new formula is also quick dissolving, opening up a potential for choking if the tablet is swallowed too slowly.

King Pharmaceuticals has no plans to change the formulation in future versions of the drug. Instead, the company has added a label warning that the drug must be taken with water. Green says, “We are just trying to get the word out to physicians to make sure that they remind their patients to take Levoxyl with plenty of water to avoid any problems where the drug might dissolve before it has been swallowed.”

*-George Koroneos*