



March 21, 2007

## ***FDA Recommends Stronger Warnings on Sedative-Hypnotics***

### **THE ISSUE**

On March 14<sup>th</sup>, 2007, the FDA requested that all manufacturers of sedative-hypnotics strengthen their prescribing information to address risks associated with the use of these drugs, including allergies and sleep-related behaviors. The drugs affected by this request are Ambien<sup>®</sup> (zolpidem tartrate), Butisol sodium<sup>®</sup> (butabarbital sodium), Carbital<sup>®</sup> (pentobarbital), Dalmane<sup>®</sup> (flurazepam HCl), Doral<sup>®</sup> (quazepam), Halcion<sup>®</sup> (triazolam), Lunesta<sup>®</sup> (eszopiclone), Placidyl<sup>®</sup> (ethchlorvynol), Prosom<sup>®</sup> (estazolam), Restoril<sup>®</sup> (temazepam), Rozerem<sup>®</sup> (ramelteon), Seconal<sup>®</sup> (secobarbital) and Sonata<sup>®</sup> (zaleplon).

### **THE RECOMMENDATION**

The FDA notified manufacturers of products used to treat sleep disorders that the labeling for such products should be revised to include warnings addressing the risk of anaphylactic reactions or angioedema, a severe facial swelling that can occur with the first dose of a sedative hypnotic, as well as complex sleep-related behaviors, during which patients make telephone calls or prepare and eat food while asleep, or sleep-driving, which is defined as driving while not fully awake after taking a sedative-hypnotic and later having no memory of having driven. The manufacturers will be sending letters to healthcare

providers beginning this week to alert them to the new warnings.

### **WHAT YOU NEED TO KNOW**

All sedative-hypnotic drugs are subject to these new warnings, although there will be variations from patient to patient in how frequently they occur, and there will be differences among the drugs in the degree of risk posed by each drug. The manufacturers of the sedative-hypnotics will be developing medication guides for distribution to patients with prescription dispensing. Patients who are more than occasionally reliant on prescription sleep aids may need encouragement to try alternative means of improving sleep quality, including better sleep hygiene and use of alternative medications, such as tricyclic antidepressants.

### **WHAT YOUR PATIENTS NEED TO KNOW**

Patients should be advised to use sedative-hypnotics for the shortest time possible. Non-pharmacologic methods of improving sleep quality should be explored; the patient should undergo a sleep study if necessary. Patients should be warned that a serious facial swelling reaction may occur even with the first dose, and that serious allergic reactions are possible. If sleep problems persist longer than a week or so, the patient should consult his or her physician for further workup.

### **RESOURCES**

FDA Press Release: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01587.html>

Fact Sheet on Sleep Disorders: <http://www.fda.gov/womens/getthefacts/sleep.html>

NHLBI Fact Sheet on Insomnia: [http://www.nhlbi.nih.gov/health/dci/Diseases/inso/inso\\_what.html](http://www.nhlbi.nih.gov/health/dci/Diseases/inso/inso_what.html)

FDA MedWatch Safety Summary: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Sedative>

### **DISCLAIMER**

This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.

