UCB, Inc. – 1950 Lake Park Drive – Smyrna, Georgia 30080

Important labeling update for Tussionex®

April 16, 2008

Dear Healthcare Provider,

UCB is informing healthcare professionals of recent changes to the Tussionex (hydrocodone polistirex/chlorpheniramine polistirex) label relating to the proper use and dosing of the product.

Since its FDA approval in 1987, Tussionex has been indicated for cough in patients 6 years of age and older. In September 2007, we notified healthcare providers of changes to the Tussionex label that included a contraindication for use in children under 6 years of age.

On March 11, 2008, the FDA approved additional labeling changes related to this contraindication and to proper dosing. Following are highlights from the updated important safety information.

- **Tussionex is contraindicated in patients less than 6 years old.** FDA has received reports of death in children less than 6 years of age who have been prescribed Tussionex. The safety and effectiveness of Tussionex have not been evaluated in children less than 6 years of age.

- **Consult the prescribing information if you need to determine the correct dose and dosing frequency of Tussionex.** Tussionex is an extended-release formulation that should not be prescribed to be taken more than once every 12 hours. Because it contains a narcotic, prescribing too high of a dose or too frequent a dose in a patient of any age can result in serious respiratory depression and possibly death.

- **Prescribers should clearly state the prescribed volume in milliliters. Pharmacists should clearly state the directions in milliliters on the prescription container, double-check volume conversions, provide a measuring device that can deliver the volume in milliliters as prescribed, and counsel patients on how to correctly measure the suspension.** Some of the reports received by FDA indicate that medication errors occurred due to the incorrect conversion from the volume prescribed by a physician to the volume indicated on the prescription label.

- **Discuss with the patient the amount of Tussionex to be given and the frequency of dosing. Instruct patients not to take, and parents not to administer, it more frequently than every 12 hours.** If the cough is not controlled, patients or parents should talk to their doctor.

Tussionex dosing instructions:

Patient age	Recommended 12-hour dose	Antitussive dose over 12 hours	Maximum dose
Children aged 6 to 11 years	2.5 mL (1/2 tsp)	5 mg hydrocodone bitartrate	Not to exceed 2 doses within 24 hours
Adults (12 years and older)	5 mL (1 tsp)	10 mg hydrocodone bitartrate	

A household teaspoon is not an accurate measuring device.

Hydrocodone, the narcotic ingredient in this medicine that controls cough, can cause life threatening breathing problems, and death, when given above, or more frequently, than the recommended dose. **Tussionex should not be used in children under 6 years of age.**

INDICATION AND IMPORTANT SAFETY INFORMATION
Tussionex is indicated for the relief of cough and upper respiratory symptoms associated with allergy or a cold in adults and children 6 years of age and older. Each 5 mL of Tussionex contains hydrocodone polistirex equivalent to 10 mg hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg chlorpheniramine maleate.

Tussionex is contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression, and in the presence of known allergy or sensitivity to hydrocodone or chlorpheniramine. The most common adverse reactions associated with Tussionex are sedation, drowsiness, and mental clouding, which may impair the mental and/or physical abilities required for potentially hazardous tasks such as driving or operating machinery. Tussionex should not be taken with alcohol or other CNS depressants. Tussionex is dosed at 5 mL every 12 hours in patients 12 years of age and older, and at 2.5 mL every 12 hours in patients 6-11 years of age. Overdose with Tussionex has been associated with fatal respiratory depression. Patients should be advised to measure Tussionex with an accurate measuring device. A household teaspoon is not an accurate measuring device. As with any other drugs in this class, the possibility of tolerance and/or dependence, particularly in patients with a history of drug dependence, should be considered.

If you have any medical questions, please contact our Medical Affairs department at (866) 822-0068, option 9.

Sincerely,

Kathleen Bos, M.D.
Vice President
U.S. Medical Affairs

Please see accompanying full Prescribing Information.