

FDA Issues Alert on Tussionex, a Long-Acting Prescription Cough Medicine Containing Hydrocodone

March 13, 2008 -- The U.S. Food and Drug Administration issued an alert today on the safe and correct use of Tussionex Pennkinetic Extended-Release Suspension in response to numerous reports of adverse events--including death--associated with the misuse and inappropriate use of this potent cough medication.

Tussionex is a prescription cough medicine containing hydrocodone, a narcotic ingredient, and the antihistamine chlorpheniramine. The product is approved for use in adults and children over the age of six years old, and should be given no more frequently than every 12 hours ("extended-release").

"There is a real and serious risk for overdosing if this medication is not used according to the labeling," said Curtis Rosebraugh, M.D., M.P.H., acting director of the FDA's Office of Drug Evaluation II. "Today's action is an example of the FDA working with drug manufacturers throughout a product's lifecycle to keep health care professionals and patients informed of new safety data."

Adverse event reports associated with Tussionex have included life-threatening side effects and deaths in patients, including children. These reports reveal physicians and other health professionals are sometimes prescribing, and patients are sometimes taking, more than the recommended dose or taking the medication more frequently than every 12 hours. The reports also show that Tussionex is sometimes prescribed or given to children less than 6 years old, for whom this medication is not approved.

Highlights of the FDA's recommendations to health care professionals include:

Tussionex should not be used (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.

Consult the prescribing information to determine the correct dose and dosing frequency of Tussionex. Tussionex is an extended-release formulation that should not be prescribed at an interval less than 12 hours.

Discuss with the patient the amount of and frequency of Tussionex to be given. Instruct patients not to take, and parents not to administer Tussionex more frequently than every 12 hours. Highlights of the FDA's recommendations to patients include:

One of the two ingredients in this long-acting cough product is hydrocodone, a narcotic. Too much hydrocodone can cause life-threatening breathing problems and death. Call your doctor right away if you have taken this medicine and have trouble breathing, slow heartbeat, severe sleepiness or cold, clammy skin.

For Tussionex, use a medicine syringe or other device designed to measure liquid medications. A household teaspoon or tablespoon should not be used because the spoons vary in size and you may receive too much or too little of the medicine. Ask your doctor or pharmacist if you are unsure how to measure the medicine.

If the cough is not controlled despite taking the prescribed dose at the recommended interval, talk to your doctor. The manufacturer of Tussionex Pennkinetic Extended-Release Suspension (UCB Inc, Smyrna, Ga.) has agreed to update the labeling, including information that Tussionex should not be prescribed to or used in children less than 6 years of age, as well as the need for accurate dosing.

For more information and the full list of the FDA's recommendations, visit <http://www.fda.gov/cder/drug/infopage/hydrocodone/default.htm>.

This alert does not impact short-acting cough products containing hydrocodone that can be given every 4 to 6 hours. However, the FDA is reviewing safety information on these other hydrocodone containing cough products and will provide updates as new information becomes available.

Source: Food and Drug Administration