

FDA NEWS RELEASE

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FDA says Tessalon liquid cough capsules pose risk for young children

Medication has candy-like appearance; should be kept in child-proof containers

The U.S. Food and Drug Administration is warning that accidental ingestion of Tessalon (benzonatate) by children younger than 10 years can result in serious side effects or death.

Tessalon, approved by the FDA to treat symptomatic relief of cough in patients older than 10, may attract younger children because of the drug's candy-like appearance – a round, liquid-filled gelatin capsule. The safety and effectiveness of benzonatate in children younger than 10 years has not been established.

"Benzonatate should be kept in a child-resistant container and stored out of reach of children," said Carol Holquist, R.Ph., director of FDA's Division of Medication Error Prevention and Analysis. "The FDA encourages health care professionals to talk with their patients and those caring for children about the risk of accidental ingestion or overdose."

A review of the FDA's Adverse Event Reporting System database from 1982 through May 2010 identified seven cases of accidental ingestion associated with benzonatate in children younger than 10. Five of the cases resulted in death in children ages 2 years and younger. Overdose with benzonatate in children younger than 2 years has been reported following accidental ingestion of only one or two benzonatate capsules.

Common adverse events reported in the overdose cases included cardiac arrest, coma, and convulsion. Signs and symptoms of overdose can occur within 15-20 minutes of ingestion. Some of the deaths reported in children have been within hours of the accidental ingestion.

The FDA is also adding a new Warning and Precaution section to the benzonatate drug label to warn health care professionals about accidental ingestion resulting in overdose and death in children younger than 10.

Consumers and health care professionals are encouraged to report adverse side effects or medication errors from the use of benzonatate to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch or by calling 800-332-1088.

For more information:

FDA 101: Medication Errors

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048644.htm>

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