# Tessalon (benzonatate): Drug Safety Communication - Potential for Accidental Ingestion by Children

U.S. Food & Drug Administration

**AUDIENCE**: Patients, Pediatrics, Pharmacy

**ISSUE**: FDA is warning the public that accidental ingestion of benzonatate by children under the age of 10 years can result in death from overdose. Overdose with benzonatate in children less than 2 years of age has been reported following accidental ingestion of as few as 1 or 2 capsules. Benzonatate may be attractive to children because of the drug's appearance (it is a round-shaped liquid-filled gelatin capsule).

**BACKGROUND**: Benzonatate is a prescription drug approved for relief of cough in patients over 10 years of age. The safety and effectiveness of benzonatate in children under 10 years of age have not been established. Benzonatate is sold under the brand-name Tessalon and is also sold in generic preparations. Individuals who experience overdose of benzonatate may exhibit restlessness, tremors, convulsions, coma, and cardiac arrest. Signs and symptoms of overdose can occur rapidly after ingestion (within 15-20 minutes). Deaths in children have been reported within hours of the accidental ingestion.

**RECOMMENDATION**: Patients who are taking benzonatate should keep the medication in a child-resistant container and store it out of reach of children. If a child accidentally ingests benzonatate, seek medical attention immediately. Signs and symptoms of benzonatate overdose can occur rapidly after ingestion (within 15-20 minutes) and may include restlessness, tremors, convulsions, coma, and cardiac arrest.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[12/14/2010 - Drug Safety Communication [3] - FDA]

SOURCE [4]

**Source URL (retrieved on *06/19/2013 - 4:13am*):**
http://www.mdtmag.com/news/2010/12/tessalon-benzonatate-drug-safety-communication-potential-accidental-ingestion-children

**Links:**
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm236651.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm236928.htm