

From the desk of Nurse Consultants

FDA Safety Changes: Children's and Infant's Advil

August 16, 2006 — The US Food and Drug Administration (FDA) has approved safety labeling revisions to advise of the risk for allergic and gastrointestinal adverse events in pediatric patients receiving ibuprofen-containing nonprescription products, such as ibuprofen plus pseudoephedrine suspension, ibuprofen plus pseudoephedrine and chlorpheniramine suspension, ibuprofen chewable tablets, and concentrated ibuprofen drops; and the increased risk for endometrial cancer in women receiving estrogen therapy.

Ibuprofen Component of Advil Pediatric Products May Cause Allergic Reactions and GI Events

On April 4, the FDA approved safety labeling revisions for nonprescription pediatric products containing ibuprofen to warn of the potential risks for allergic reactions, and gastrointestinal (GI) adverse events associated with their use in children aged younger than 12 years.

The warnings apply to over-the-counter (OTC) products, such as ibuprofen plus pseudoephedrine 100-mg/15-mg per 5-mL suspension (*Children's Advil Cold*); ibuprofen plus pseudoephedrine and chlorpheniramine 100-mg/15-mg/1-mg per 5-mL suspension (*Children's Advil Allergy Sinus*); ibuprofen 50- and 100-mg chewable tablets (*Children's Advil Chewables and Junior Strength Advil Chewables*); and concentrated ibuprofen 50-mg/1.25-mL drops (*Infant's Advil*, all made by Wyeth Consumer Healthcare).

Source: Medscape

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