

KPP *Klinical Update*

February 28th, 2012

Dosing Children with OTC Cough and Cold Medications

Before the 1970's there was little information available to parents regarding the safety of using over-the-counter cold and cough preparations in children. Due to the thalidomide calamity in the 1950's and 60's, congress passed an amendment to the Pure Food and Drug Law which gave the Food and Drug Administration (FDA) more power to regulate pharmaceutical companies. One area the FDA focused on was mandating more thorough testing of the safety and efficacy of medications prior to their release to the market. More specifically, the FDA required drug companies to thoroughly review and provide recommendations for medications that are used by pregnant or lactating women, the elderly, and children. Presently, for a manufacturer to market a "pediatric" formulation, they must test the product in several age groups: six to 12, two to six, and younger than two years of age. When the marketing/labeling changes were first mandated, a visit to the pharmacy was a frustrating experience for parents because most product said "ask your doctor" before giving this product to someone under the age of 12. However, over time, the manufacturers have completed the testing necessary to comply with the FDA regulations and now give specific instructions for the different age groupings.



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Tips to Safely Dose Children with OTC Cold and Cough Medicines

- Always use products intended for the age of the child
- Always read and follow the label exactly
- Always use the measuring device supplied with the medication
- Only use the medicine which treats the symptoms the child is experiencing
- Do NOT use products with the intent of sedating the child
- Do NOT use products containing aspirin
- Be very careful using more than one product because many formulations contain the same ingredients
- Don't guess! Ask your doctor or pharmacist any questions that arise

The Mayo Clinic's Guide on When to Call the Doctor

Call the doctor if the infant:

- Isn't wetting as many diapers as usual
- Has a temperature higher than 102° F for one day
- Has a temperature higher than 101° F for more than 3 days
- Seems to have ear pain
- Has red eyes or develops yellow eye discharge
- Has a cough for more than one week
- Has thick, green nasal discharge for more than two weeks
- Has any signs or symptoms that worry you