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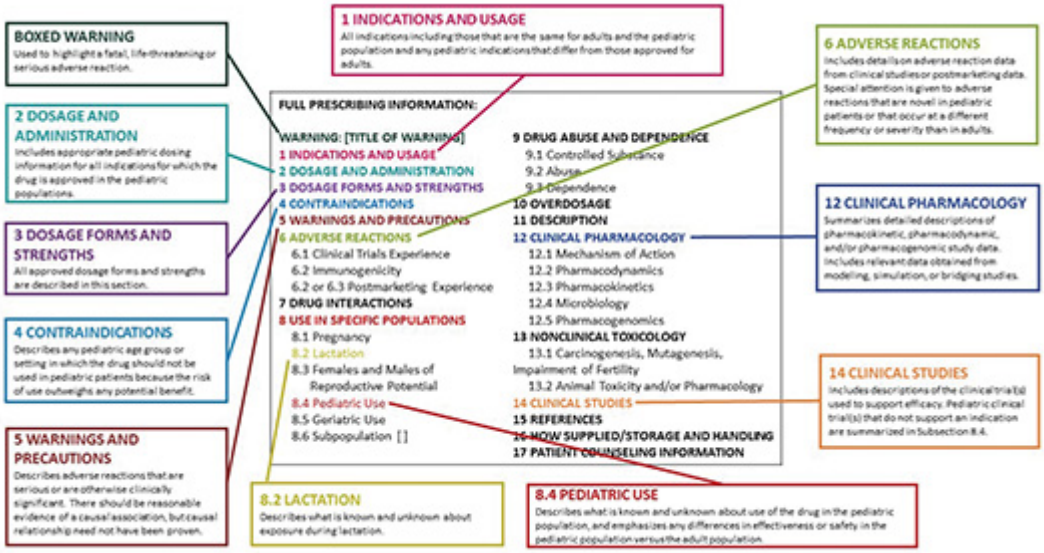
Drug labels include information on use in pediatric patients

by the Food and Drug Administration's Office of Pediatric Therapeutics and Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health

The Physician Labeling Rule (PLR) outlines the content and format of prescribing information for all new prescription drugs and biologics (and supplemental applications) approved on or after June 30, 2001.

PLR-compliant labeling includes:

- Highlights (a concise summary of crucial prescribing information),
- Table of Contents and
- Full Prescribing Information (FPI), which is organized into 17 standardized sections (see figure).



Among the sections is one on Use in Specific Populations, which includes subsection 8.4, Pediatric Use.

When evidence supports the safety and effectiveness for an indication in pediatric patients (either all patients or a specific age group), pediatric use information must be included in all relevant sections of labeling.

When evidence is *insufficient* to support a pediatric indication, all relevant pediatric information from pediatric studies submitted to the Food and Drug Administration is placed only in the Pediatric Use subsection so as not to imply an approved pediatric indication. However, if evidence suggests that a drug would be unsafe in a specific pediatric age group(s), this information is included in other sections of labeling, such as Contraindications and Warnings and Precautions, as appropriate.

Pediatric labeling is intended to provide information for prescribers on the safe and effective use of medications in their patients.

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