

Changes to Infants and Children's Liquid Acetaminophen

The makers of single-ingredient liquid acetaminophen for infants and children are making changes to the medicine to make it easier for parents and caregivers to use the medicines and to avoid possible dosing errors. The medicines will now be made in only one strength (as opposed to the three different strengths previously available) and will have age-appropriate dosing directions and devices with each package.

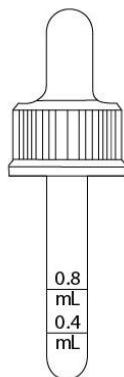
You have already started to see the new products on store shelves, and the transition will continue through early 2012. While this transition occurs, there may be different concentrations of single-ingredient liquid acetaminophen for infants and children on store shelves or in your medicine cabinets.

What you should know about these changes:

- Single-ingredient liquid acetaminophen is the **most commonly used medicine to treat pain and fever in children**. This medicine will continue to be marketed separately for infants (under age 3) and children (ages 2 to under 12).
- Previously, infants' liquid acetaminophen came in concentrated drops: 80 milligrams of acetaminophen per 0.8 mL (80mg/0.8mL) or 80 milligrams per 1.0 mL (80mg/1.0mL). Now, **all** pediatric liquid acetaminophen – infants' and children's – will be **one consistent strength, 160 mg/5mL** (which is current strength of the children's acetaminophen medicines). Manufacturers will no longer make a unique "concentrated drops" product for infants, rather the concentration for infants under age 3 will now be same as for older children, but with new age-appropriate delivery devices and dosing instructions.
- Both infants and children's single-ingredient acetaminophen products will now have age-appropriate dosing devices. Previously, a dropper was enclosed to administer the medicine. Now, all infants' single-ingredient liquid acetaminophen products – which contain the lower concentration – will include a **plastic syringe** to administer medicines by mouth. An image of the new and old devices is included below. All children's single-ingredient liquid acetaminophen products will include a small plastic **measuring cup** for easy, convenient use.

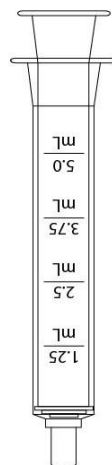
Old Infant Dosing Device:

Dropper



New Infant Dosing Device:

Syringe



Standard Child Dosing Device:

Measuring Cup



- Both the old and new infants' concentrations are **safe and effective when used as labeled**.
- As always, parents should **carefully read and follow the [Drug Facts label](#)** since several concentrations of infants' single-ingredient liquid acetaminophen could be on store shelves and in the home. The new products may have a "new" or "new dosing instructions" banner or flag on the front panel on the package.
- For children under 2 years of age, parents and caregivers must consult their healthcare provider for dosing instructions. The Drug Facts label on the packaging does not include dosing instructions for this age group. Your pediatrician can provide you with your child's age and weight appropriate dose via a phone call or office visit.
- Infants' products will now have an additional safety feature. The bottles are now made with flow restrictors to limit the volume of medicine that can be poured out. This is to prevent accidental ingestion, should a child get into medicine when a parent isn't looking.

Weight	Infants' Acetaminophen			Children's Acetaminophen
	Old Concentration via Dropper		New Concentration via Syringe (160 mg/5 mL)	Standard Concentration via Measuring Cup (160 mg/5 mL)
	(80 mg/0.8 mL)	(80 mg/1 mL)		
6-11 lbs.	0.4 mL	0.5 mL	1.25 mL	
12-17 lbs.	0.8 mL	1.0 mL	2.5 mL	2.5 mL
18-23 lbs.	1.2 mL	1.5 mL	3.75 mL	3.75 mL
24-35 lbs.	1.6 mL	2.0 mL	5 mL	5 mL
36-47 lbs.		3.0 mL		7.5 mL
48-59 lbs.				10 mL
60-71 lbs.				12.5
72-95 lbs.				15 mL
96+ lbs.				20 mL

