

Know Concentration Before Giving Acetaminophen to Infants

The Food and Drug Administration (FDA) is urging consumers to carefully read the labels of liquid acetaminophen marketed for infants to avoid giving the wrong dose to their children.

A less concentrated form of the popular medication is arriving on store shelves, and giving the wrong dose of acetaminophen can cause the medication to be ineffective if too little is given or cause serious side effects and, possibly, death if too much is given.

In an attempt to reduce the confusion over different strengths that have been blamed for past overdoses, some manufacturers are voluntarily offering only the less concentrated version for all children.

Until now, liquid acetaminophen marketed for infants has only been available in a stronger concentration that doesn't require giving the infants as much liquid with each dose.

But right now both concentrations of liquid acetaminophen are in circulation. Before giving the medication, parents and caregivers need to know whether they have the less concentrated version or the older, more concentrated medication. FDA is concerned that infants could be given too much or too little of the medicine if the different concentrations of acetaminophen are confused.

"Be very careful when you're giving your infant acetaminophen" says Carol Holquist, director of FDA's Division of Medical Error Prevention and Analysis.

Here's what the agency wants parents and caregivers to do:

More concentrated, still available

Drug Facts	
Active Ingredient (in each 0.8 mL)	Purpose
Acetaminophen 80 mg.....	Pain reliever/fever reducer

Drug Facts	
Active Ingredient (in each 1.0 mL)	Purpose
Acetaminophen 80 mg.....	Pain reliever/Fever reducer

Less concentrated, newly available

Drug Facts	
Active Ingredient (in each 5 mL)	Purpose
Acetaminophen 160 mg.....	Pain reliever/Fever reducer

- Read the Drug Facts label on the package very carefully to identify the concentration of the liquid acetaminophen, the correct dosage, and the directions for use.
- Do not depend on a banner proclaiming that the product is "new." Some medicines with the old concentration also have this headline on their packaging.
- Use only the dosing device provided with the purchased product in order to correctly measure the right amount of liquid acetaminophen.
- Consult your pediatrician before giving this medication and make sure you're both talking about the same concentration.

Overdosing Has Been a Risk

An April 2011 report from FDA's Center for Drug Evaluation and Research (CDER) found that confusion caused by the different concentrations of liquid acetaminophen for infants and children was leading to overdoses that made infants seriously ill, with some dying from liver failure.

So to avoid dosing errors, some manufacturers voluntarily changed the liquid acetaminophen marketed for infants from 80 mg per 0.8mL or 80 mg per 1 mL to be the same concentration as the liquid acetaminophen marketed for children—160 mg per 5mL. This less concentrated liquid acetaminophen marketed for infants now has new dosing directions and

“Be very careful when you’re giving your infant acetaminophen.”

may have a new dosing device in the box, such as an oral syringe.

But this is a voluntary change and some of the older, stronger concentrations of acetaminophen marketed for infants are still available and may remain available.

“There is still some on store shelves; there is still some in homes; and there is still some in distribution,” says Holquist.

Why does this pose a danger?

If a pediatrician prescribes a 5 mL dose of the less concentrated liquid acetaminophen, but the parents administer a 5 mL dose of the more concentrated liquid acetaminophen, the child can receive a potentially fatal overdose during the course of therapy, Holquist explains.

Conversely, if a physician prescribes a dose based on the more concentrated liquid acetaminophen and the less concentrated medication is used, the child might not receive enough medication to fight a fever, she says.

FDA has issued a Drug Safety Communication (www.fda.gov/Drugs/DrugSafety/ucm284741.htm) with more information for consumers about how to avoid confusion and potential dosing errors with the different concentrations of liquid acetaminophen.

What Should You Do?

Adding to the confusion is the fact that the box and the bottle may look much the same for both old and new versions of the medication, Holquist says.

Read the Drug Facts label to tell the difference between the two liquid acetaminophen products:

- Look for the “Active ingredient” section of the Drug Facts label usually printed on the back of an over-the-counter medication package.
- If the package says “160 mg per 5 mL” or “160 mg (in each 5 mL)”, then this is the less concentrated liquid acetaminophen. This medication should come with an oral syringe to help you measure the dose.
- If the package says “80 mg per 0.8 mL” or “80 mg per 1 mL,” then this is the more concentrated liquid acetaminophen. This product may come with a dropper.

If the dosing instructions provided by your healthcare provider differ from what is on the label, check with a healthcare professional before administering the medication. Do not rely on dosing information provided from other sources such as the Internet, old dosing charts, or family members.

It is important to understand that there is no dosing amount specified for children younger than 2 years of age. If you have an infant or child younger than 2 years old, always check with your healthcare provider for dosing instructions.

Acetaminophen is marketed for infants under brand names such as Little Fevers Infant Fever/Pain Reliever, Pedia Care Fever Reducer Pain Reliever and Triaminic Infants’ Syrup Fever Reducer Pain Reliever. There are also store brands on the shelves.

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