

Important Update

Dosing and Concentration Changes for OTC Infants' Acetaminophen Products

Frequently Asked Questions

Why was the change in concentration for infants' acetaminophen products made?

The purpose of this industry-wide transition is to help minimize the potential for medication errors due to confusion between infants' and children's acetaminophen products having different concentrations. This transition is consistent with an FDA Advisory Committee recommendation made in 2009 to offer a single concentration of acetaminophen for children.

Has the mg/kg dose for infants' acetaminophen products changed?

No, the mg/kg dose has NOT changed. The recommended dose of acetaminophen continues to be 10-15mg/kg. However, because the acetaminophen concentration in the infants' formulation has changed, dosing on a volume-per-weight (or volume-per-age) basis has changed. The amount of acetaminophen is the same; it is now being delivered in a larger volume of liquid.

Are any manufacturers going to continue to produce an infants' acetaminophen concentrated drops product?

No. This change is an industry-wide initiative. It is important to be aware that there will be a time period when both the old and new concentrations of infants' products may be available on store shelves and in medicine cabinets. We ask for your support in proactively discussing this change with parents and caregivers. It is important that you and your staff always verify the product concentration parents and caregivers are using before providing dosing directions.

When will this transition take place?

The transition of other manufacturers' infants' products to 160mg/5mL is already taking place and is anticipated to continue into 2012. It is important to be aware that there will be a time period when both the old and new concentrations of infants' acetaminophen liquid products may be available on store shelves and in medicine cabinets.

Should parents and caregivers be instructed to discard old infants' concentrated product?

Parents can continue to use infants' acetaminophen products as directed by the package label or their healthcare professional. Please remember to always verify the product concentration parents and caregivers are using before providing dosing directions.

Will infants' acetaminophen concentrated drops be offered in the hospitals?

No. This change is an industry-wide initiative and applies to all retail stores and hospitals.

If I have responsibilities in an institution, such as a hospital or clinic, what else do I need to consider in this transition?

There may be a period of time when both concentrations of infants' acetaminophen will be stocked in institutions. Please verify the formulation being used before writing dosing orders to the nursing staff.

Where can I request a new infants' acetaminophen dosing chart or other in-office materials?

To request a new infants' acetaminophen dosing chart or other in-office materials, go to www.tylenolprofessional.com and sign in to order. If you have any additional questions or concerns, please contact our Consumer Care Center at 1-888-892-6100, Monday through Friday, 8:00 am to 8:00 pm ET.

Are Children's and Infants' TYLENOL® products available on store shelves?

Infants' TYLENOL® is not currently available, however, Children's TYLENOL® and Children's TYLENOL® Meltaways are available on store shelves. Parents can go to our store locator on www.tylenol.com to find where product is available in their area. Infants' TYLENOL® will be available as early as this upcoming cold and flu season.

Will there be any changes to children's acetaminophen dosing?

No, this change is for infants' acetaminophen liquid products only.

Will there be any changes to children's ibuprofen dosing?

No, this change is for infants' acetaminophen liquid products only.



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