

Dear Health Care Professional:

I would like to inform you that many manufacturers and retailers of pediatric acetaminophen solid dose medicines including Johnson & Johnson Consumer Inc., the makers of Children's TYLENOL®, are transitioning to a single strength of 160 mg chewables in the United States.

This transition is consistent with a 2011 FDA Advisory Committee recommendation that the FDA consider a single strength for solid pediatric acetaminophen products. It is intended to help minimize the potential for medication errors due to confusion between multiple strengths.

The following are some important points related to this topic for you to be aware of:

- Currently the marketplace includes pediatric acetaminophen chewable products available in both 80 mg and 160 mg strengths. These are commonly referred to as "Children's" and "Jr" respectively.
- Many manufacturers and retailers will be transitioning to one 160 mg strength to be named "Children's". This dosage strength aligns with the most common single ingredient pediatric liquid acetaminophen medicine concentration (160 mg/5mL).
- As manufacturers and retailers make this transition, there will still be some solid dose chewable products labeled as "Children's" available in the marketplace and in medicine cabinets at the 80 mg strength as well as product labeled as "Junior" at the 160 mg strength.
- The pediatric acetaminophen products currently on the market can continue to be used as labeled.
- The in-store transition to the single strength 160 mg acetaminophen chewable products will begin in early 2017 and is anticipated to continue throughout 2017. However, the transition within any caregivers' medicine cabinet may take considerably longer.

! IMPORTANT

- Always verify the product strength a parent or caregiver is using before providing dosing directions.
- Remind caregivers to always read and follow the Drug Facts label dosing directions of the specific medication that they are using.

• We ask your support in proactively discussing this with parents and caregivers and ask that you and your staff remind caregivers to always read and follow the Drug Facts label dosing directions of the specific medication that they are using.

• Please always verify the acetaminophen product strength (160 mg or 80 mg) a parent or caregiver is using before providing dosing directions.

If you have any questions pertaining to the above, please feel free to contact me at ekuffner@its.jnj.com. We greatly appreciate your continued support.

Sincerely,

Edwin K. Kuffner, MD

Vice President, Global Medical Affairs & Clinical Research

Johnson & Johnson Consumer Inc.

1. Why is this change being made?

This transition is consistent with a 2011 FDA Advisory Committee recommendation that the FDA consider a single strength for solid pediatric acetaminophen products. The decision to only offer the 160mg strength was based upon a number of factors: 1) the 160 mg is currently the most widely used solid oral dosage strength; 2) this dosage strength aligns with the most common single ingredient pediatric liquid acetaminophen medicine concentration (160mg/5mL); and 3) the need to take fewer tablets per dose is likely to improve dosing compliance, especially for older children, who are more likely to use the solid dosage forms.

2. Is it still safe for my patients to use the 80mg product?

The pediatric acetaminophen products currently on the market can continue to be used as labeled. Please remind your parents/caregivers to always read and follow the entire Drug Facts label.

3. Are all manufacturers and retailers making this change?

Each individual manufacturer and retailer ultimately has to decide on its own on whether to make the change to manufacture only the 160mg strength pediatric acetaminophen product. This change has support from a broad range of stakeholders.

4. When will all of the manufacturers and retailers transition?

Each individual manufacturer and retailer ultimately has to decide on its own on whether to make the change to manufacture or sell only the 160mg strength pediatric acetaminophen product.

5. How do I recommend dosing if I don't know what product the caregiver/parent has or will purchase?

Please always verify the acetaminophen dosage strength (80mg or 160mg) a parent is using before providing dosing directions. Always remind caregivers/parents to read and follow the Drug Facts label dosing directions of the specific medication that they are using. Please also remind them to always keep the medicine in its original container as it contains the full labeling instructions and strength for the product.

Sample Language To Communicate Pediatric Acetaminophen Solid Dose (Chewable) Change

NEWSLETTER

IMPORTANT ANNOUNCEMENT: Many manufacturers and retailers of pediatric acetaminophen solid dose medicines are transitioning to a single strength of 160 mg chewables in the United States.

The following are some important points related to this topic for you to be aware of:

- Currently the marketplace includes pediatric acetaminophen chewable products available in both 80 mg and 160 mg strengths. These are commonly referred to as “Children’s” and “Jr” respectively.
- Many manufacturers and retailers will be transitioning to one 160 mg strength to be named “Children’s”. This dosage strength aligns with the most common single ingredient pediatric liquid acetaminophen medicine concentration (160 mg/5mL).
- During this time of transition, there will still be some solid dose chewable products labeled as “Children’s” available in the marketplace and in medicine cabinets at the 80 mg strength as well as product labeled as “Junior” at the 160 mg strength.
- The pediatric acetaminophen products currently on the market can continue to be used as labeled.
- The in-store transition to the single strength 160 mg acetaminophen chewable products will begin in early 2017 and is anticipated to continue throughout 2017. However, the transition within any caregivers’ medicine cabinet may take considerably longer.

We ask your support in proactively discussing this with parents and caregivers and ask that you and your staff remind caregivers to always read and follow the Drug Facts label dosing directions of the specific medication that they are using .

Please always verify the acetaminophen product strength (160 mg or 80 mg) a parent or caregiver is using before providing dosing directions.

SOCIAL MEDIA POSTS

- Dosing directions have changed for some pediatric acetaminophen chewable products. Always verify the product strength (160 mg or 80 mg) a parent/caregiver is using before providing dosing directions. Remind them to always read and follow the labeled dosing directions of the specific medicine they are using.
- Many pediatric acetaminophen solid dose manufacturers and retailers are transitioning to a single strength of 160 mg. During this transition, there will be both 80 and 160mg strengths in the market. Always verify the product strength (160 mg or 80 mg) a parent/caregiver is using before providing dosing directions. Remind them to always read and follow the labeled dosing directions of the specific medicine they are using.

Pediatric Acetaminophen Solid Dose (Chewable) Strength Change

Many pediatric acetaminophen solid dose manufacturers and retailers are transitioning to a single strength of 160 mg, and there are new dosing directions for these products for some age groups.











What you should know:

- Currently the marketplace includes pediatric acetaminophen chewable products available in both 80 mg and 160 mg strengths. These are commonly referred to as “Children’s” and “Jr” respectively.
- Many manufacturers and retailers will be transitioning to a single strength of 160 mg strength to be named “Children’s”.
- During this time of transition, there will still be some solid dose chewable products labeled as “Children’s” available in the marketplace and in medicine cabinets at the 80 mg strength as well as product labeled as “Junior” at the 160 mg strength.

What you can do:

1. Proactively discuss this with parents and caregivers.
2. Always verify the acetaminophen product strength (160 mg or 80 mg) a parent or caregiver is using before providing dosing direction.
3. Identify the product strength and dose for your patient’s weight/age from the appropriate chart below.

Pediatric Acetaminophen Solid Dose (Chewable) Dosing Chart

		Pediatric (80 mg) Dosage Units		Pediatric (160 mg) Dosage Units	
Age (years)	Weight (pounds)	Number of Dosage Units (80 mg chewable tablets)	Total Dosage (mg)	Number of Dosage Units (160 mg chewable tablets)	Total Dosage (mg)
<2 years	<24 pounds	No recommended dosage except under the direction of a healthcare professional		No recommended dosage except under the direction of a healthcare professional	
2-3 years	24-35 pounds	2 	160	1 	160
4-5 years	36-47 pounds	3 	240	1 ½ 	240
6-8 years	48-59 pounds	4 	320	2 	320
9-10 years	60-71 pounds	5 	400	2 ½ 	400
11 years	72-95 pounds	6 	480	3 	480



REMINDE PARENTS AND CAREGIVERS: Always read and follow the labeled dosing directions of the specific medicine they are using and keep the medicine in its original container. Keep medicines out of the reach of children.