

INFANTS TYLENOL- acetaminophen suspension

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Infants' TYLENOL

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - toothache

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if your child has liver disease

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

When using this product do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use.**
- **do not give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening
- flip bottle upside down. Pull yellow part of syringe to correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL

* or as directed by a doctor

Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

Other information

- store between 20-25°C (68-77°F)
- **do not use if carton tape or bottle wrap imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

anhydrous citric acid, D&C red no. 33, FD&C blue no. 1, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

call **1-800-458-1635** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-433-01

Infants'
TYLENOL®
For Children

Acetaminophen 160 mg per 5 mL Oral Suspension
Pain Reliever-Fever Reducer

Pain + Fever
Infants

Alcohol Free
Ibuprofen Free
Aspirin Free
No Parabens

SimpleMeasure®
Specially designed for younger children

Use Only Enclosed Syringe

1 fl oz (30 mL)
160 mg per 5 mL*

Grape Flavor

*Same as Children's TYLENOL



How can we help?
 ☎ 1-800-458-1635



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Drug Facts

Active ingredient (in each 5 mL) **Purpose**
 Acetaminophen 160 mg.....Pain reliever/fever reducer

Uses temporarily:
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Do not use
 ■ with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 ■ if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has liver disease
 Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

When using this product do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if ■ pain gets worse or lasts more than 5 days
 ■ fever gets worse or lasts more than 3 days
 ■ new symptoms occur ■ redness or swelling is present
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Drug Facts (continued)

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Dosing Chart

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 Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

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Inactive ingredients
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NDC 50580-433-01

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 For Children
 Acetaminophen 160 mg per 5 mL Oral Suspension
 Pain Reliever-Fever Reducer
Pain + Fever
 Infants

Alcohol Free
 Ibuprofen Free
 Aspirin Free
 No Parabens



SimpleMeasure®
 Specially designed for younger children

1 fl oz (30 mL)
 160 mg per 5 mL*

Use Only Enclosed Syringe
Grape Flavor

*Same as Children's TYLENOL

Infants' TYLENOL®
 For Children
 Pediatricians recommend TYLENOL® for pain and fever

Actual Size

IMPORTANT:
 Please see dosing chart or ask a doctor for your child's correct dose

SimpleMeasure®

STEP 1. Push air out of syringe

STEP 2. Insert syringe tip into bottle opening

STEP 3. Flip bottle upside down

STEP 4. Pull yellow part of syringe to correct dose

LOT:

EXP:

Distributed by:
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 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA ©J&JCI 2019
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USA
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INFANTS TYLENOL

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-433
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
glycerin (UNII: PDC6A3C0OX)	
high fructose corn syrup (UNII: XY6UN3QB6S)	
microcrystalline cellulose (UNII: OP1R32D61U)	
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol solution (UNII: 8KW3E207O2)	
sucralose (UNII: 96K6UQ3ZD4)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE (reddish-purple)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-433-01	1 in 1 CARTON	08/07/2017	
1		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-433-02	1 in 1 CARTON	09/29/2017	
2		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/07/2017	

Revised: 11/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division