

INFANTS TYLENOL- acetaminophen suspension

Johnson & Johnson Consumer Inc.

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

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Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes
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 ■ with other drugs containing acetaminophen
Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash
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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.

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Drug Facts (continued)

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Dosing Chart

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NDC 50580-433-01

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

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



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

LOT:

EXP:

Distributed by:
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 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA ©J&JCI 2019
 Visit us at www.tylenol.com 30044750

USA
 691286
 965



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
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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 Drug	M013	08/07/2017	

Revised: 7/2024

Johnson & Johnson Consumer Inc.