

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, flavors, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol solution, sucralose, sucrose, xanthan gum

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-599-03

Infants'
TYLENOL®
For Children

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

DYE-FREE

Pain+Fever

Infants

Free Of:

- Dyes
- Alcohol
- Ibuprofen
- Aspirin
- Parabens
- High Fructose

Corn Syrup

SimpleMeasure®
Specially designed for younger children
Use Only Enclosed Syringe

*Same as Children's TYLENOL

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

Cherry
Flavor

INFANTS TYLENOL			
acetaminophen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-599
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
XANTHAN GUM (UNII: TTV12P4NEE)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
GLYCERIN (UNII: PDC6A3C0OX)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
WATER (UNII: 059QF0KO0R)			
SORBITOL SOLUTION (UNII: 8KW3E207O2)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SUCROSE (UNII: C151H8M554)			
Product Characteristics			
Color	white (Dye Free)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-599-01	1 in 1 CARTON	06/26/2017	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-599-03	1 in 1 CARTON	04/20/2020	
2		30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:50580-599-02	2 in 1 CARTON	03/24/2022	
3		30 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	06/26/2017	

Labeler - Johnson & Johnson Consumer Inc. (878046358)