

**INFANTS TYLENOL- acetaminophen suspension**  
**Kenvue Brands LLC**

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**Infants' TYLENOL<sup>®</sup>**

***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**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL) *</b>
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: PDC6A3C00X)				
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		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	06/26/2017	

**Labeler -** Kenvue Brands LLC (118772437)

Revised: 2/2025

Kenvue Brands LLC