

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

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**Children's 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 below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL) *</b>
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-95	11 years	15 mL

\* or as directed by a doctor

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

### **Other information**

- each 5 mL contains: **sodium 2 mg**
- 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 50580-612-01

Children's  
TYLENOL®

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

Pain+Fever  
Ages 2-11 Years

Alcohol Free  
Ibuprofen Free  
Aspirin Free  
No Parabens

4 fl oz (120 mL)  
160 mg per 5 mL

Grape  
Flavor



How can we help?  
**1-800-458-1635**

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# Children's **TYLENOL**

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Alcohol Free  
Ibuprofen Free  
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# Children's **TYLENOL**

- ✔ **Pediatricians recommend TYLENOL® for pain and fever**
- ✔ **Relied on by moms for over 60 years**

### DIRECTIONS:

**STEP 1.**  
Shake well  
before using



**STEP 2.**  
Remove child  
protective  
cap



**STEP 3.**





4 fl oz (120 mL)  
160 mg per 5 mL

**Grape**  
Flavor

Squeeze your child's dose into the dosing cup

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



LOT:

EXP:



USA  
692013  
905

Drug Facts	
Active ingredient	Purpose

Drug Facts (continued)
Directions

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

**Uses** temporarily:

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**Questions or comments?**

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Distributed by:

30044842/692013

**JOHNSON & JOHNSON CONSUMER INC.**

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

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**CHILDRENS TYLENOL**

acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-612
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	purple	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-612-01	1 in 1 CARTON	08/01/2016	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:50580-612-02	2 in 1 PACKAGE	10/03/2016	
2		1 in 1 CARTON		
2		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

**Marketing Information**

<b>Marketing</b>	<b>Application Number or Monograph</b>	<b>Marketing Start</b>	<b>Marketing End</b>
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Category	Citation	Date	Date
OTC Monograph Drug	M013	08/01/2016	

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

Revised: 9/2024

Kenvue Brands LLC