

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

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**Children's 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 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, FD&C red no. 40, 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 50580-509-01

Children's  
TYLENOL®

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

Pain+Fever

Ages 2-11 Years

No Parabens  
Ibuprofen Free  
Alcohol Free  
Aspirin Free

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

Strawberry  
Flavor



How can we help?  
 ☎ 1-800-458-1635

**Drug Facts**

**Active ingredient** **Purpose**  
 (in each 5 mL)  
 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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■ with other drugs containing acetaminophen  
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**Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin**

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**Drug Facts (continued)**

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**JOHNSON & JOHNSON CONSUMER INC.**  
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 Fort Washington, PA 19034 USA  
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 Visit us at [www.tylenol.com](http://www.tylenol.com)

NDC 50580-509-01

**Children's**  
**TYLENOL**

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

**Pain + Fever**  
**Ages 2-11 Years**

No Parabens  
 Ibuprofen Free  
 Alcohol Free  
 Aspirin Free

4 fl oz (120 mL) **Strawberry**  
 160 mg per 5 mL *Flavor*



**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:**  
 Squeeze your  
 child's dose  
 into the  
 dosing cup



**IMPORTANT:**

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

**CHILDRENS TYLENOL**

acetaminophen suspension

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:50580-509

**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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-509-01	1 in 1 CARTON	01/16/2017	
1		120 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	01/16/2017	

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