

**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 50580-614-01

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  
Cherry  
Flavor



How can we help?  
 ☎ 1-800-458-1635

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



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

**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:  
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 ■ sore throat ■ toothache

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**Drug Facts (continued)**

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**Questions or comments?**  
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## CHILDRENS TYLENOL

acetaminophen suspension

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:50580-614 |
| <b>Route of Administration</b> | 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   | CHERRY | Imprint Code |  |
| Contains |        |              |  |

**Packaging**

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50580-614-01 | 1 in 1 CARTON   | 08/01/2016           |                    |
| 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                                     | 08/01/2016           |                    |

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