

**INFANTS TYLENOL- acetaminophen suspension**  
**Johnson & Johnson Consumer Inc.**

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**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, 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 50580-433-01

Infants'  
TYLENOL®  
For Children

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

Pain + Fever  
Infants

Alcohol Free  
Ibuprofen Free  
Aspirin Free  
No Parabens

SimpleMeasure®

Specially designed for younger children

Use Only Enclosed Syringe

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

Grape Flavor

\*Same as Children's TYLENOL

| INFANTS TYLENOL  |                         |  |                      |                    |
|--|-------------------------|--|----------------------|--------------------|
| acetaminophen suspension   |                         |  |                      |                    |
|  |                         |  |                      |                    |
| Product Information  |                         |  |                      |                    |
| Product Type   | HUMAN OTC DRUG          | Item Code (Source)                                       | NDC:50580-433        |                    |
| 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)                           |                         |  |                      |                    |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)                                  |                         |  |                      |                    |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                                 |                         |  |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)  |                         |  |                      |                    |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)                        |                         |  |                      |                    |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                      |                         |  |                      |                    |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) |                         |  |                      |                    |
| WATER (UNII: 059QF0K00R)   |                         |  |                      |                    |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                                 |                         |  |                      |                    |
| SORBITOL SOLUTION (UNII: 8KW3E207O2)                               |                         |  |                      |                    |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                                       |                         |  |                      |                    |
| XANTHAN GUM (UNII: TTV12P4NEE)                                     |                         |  |                      |                    |
|  |                         |  |                      |                    |
| Product Characteristics  |                         |  |                      |                    |
| Color  | purple (reddish-purple) |  | Score                |                    |
| Shape  |                         |  | Size                 |                    |
| Flavor   | GRAPE                   |  | Imprint Code         |                    |
| Contains   |                         |  |                      |                    |
|  |                         |  |                      |                    |
| Packaging  |                         |  |                      |                    |
| #  | Item Code               | Package Description                                      | Marketing Start Date | Marketing End Date |
| 1  | NDC:50580-433-01        | 1 in 1 CARTON  | 08/07/2017           |                    |
| 1  |                         | 30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package |                      |                    |
| 2  | NDC:50580-433-02        | 1 in 1 CARTON  | 09/29/2017           |                    |
| 2  |                         | 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                                     | 08/07/2017           |                    |

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 2/2024

Johnson & Johnson Consumer Inc.