# CHILDRENS TYLENOL- acetaminophen suspension Kenvue Brands LLC

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Children's Tylenol®

**Drug Facts** 

# **Active ingredient**

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

# **Purpose**

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Pain reliever/fever reducer

#### Uses

**Uses** temporarily:

- reduces fever
- relieves minor aches and pains due to:
- -the common cold
- -flu
- -headache
- -sore throat
- -toothache

# **Warnings**

# Liver warning

**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**

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- 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
- $\blacksquare$  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

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL

48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	11 years	15 mL

<sup>\*</sup> 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

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- each 5 mL contains: potassium 5 mg
- store between 20-25°C (68-77°F)
- do not use if carton is opened. Do not use if 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, sodium benzoate, sodium citrate, sorbitol solution, sucralose, sucrose, xanthan gum

**Questions or comments?** call **1-800-458-1635** (toll-free) or **215-273-8755** (collect)

NDC 50580-139-04

**NEW** 

Children's TYLENOL®

Acetaminophen (160 mg per 5 mL)

Oral Suspension

Pain Reliever-Fever Reducer

Pain+Fever

Ages 2-11 Years

**DYE-FREE** 

# Free Of:

- Dyes
- Alcohol
- Ibuprofen
- Aspirin
- Parabens
- High Fructose Corn Syrup

Artificial Flavoring

# Natural Apple Flavor with Other Natural Flavors

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



## acetaminophen suspension

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-139

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACCURATION OF THE CONTROL OF THE CON	26200ITLOD) ACETAMBLODUEN	160 : - 1

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 160 mg in 5 mL

# **Inactive Ingredients**

Ingredient Name	Strength
SODIUM CITRATE (UNII: 107302IUI B)	

SUDIUM CITRATE (UNII: 1Q/3Q2JULK)

SUCROSE (UNII: C151H8M554)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

SUCRALOSE (UNII: 96K6UQ3ZD4)

XANTHAN GUM (UNII: TTV12P4NEE)

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)

**GLYCERIN** (UNII: PDC6A3C0OX)

**SORBITOL SOLUTION** (UNII: 8KW3E207O2) **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL)

**SODIUM BENZOATE** (UNII: OJ245FE5EU)

WATER (UNII: 059QF0KO0R)

#### **Product Characteristics**

Color	white (White to off-white)	Score
Shape		Size
Flavor	APPLE	Imprint Code
Contains		

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-139- 04	1 in 1 CARTON	04/28/2025	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M013	04/28/2025	

# Labeler - Kenvue Brands LLC (118772437)

Revised: 4/2025 Kenvue Brands LLC