# CHILDRENS PAIN AND FEVER- acetaminophen suspension CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

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CVS 44-097

# Active ingredient (in each 5 mL)

Acetaminophen 160 mg

# **Purpose**

Pain reliever/fever reducer

#### Uses

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

# 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.

# 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.

## 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
- redness or swelling is present
- any new symptoms appear

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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
- shake well before using
- mL = milliliter
- only use the dose cup provided
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- 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	Ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 mL
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

<sup>\*</sup>or as directed by a doctor

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

# Inactive ingredients

anhydrous citric acid, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

## Questions or comments?

1-800-426-9391

# Principal display panel

#### **VCVS**

Health®

Compare to the active ingredient in Children's Tylenol® Oral Suspension†

## **Oral Suspension**

Children's Pain & Fever ACETAMINOPHEN 160 mg / 5 mL

Pain reliever; Fever reducer

Ages 2 to 11 years

- Free of alcohol
- Aspirin Free
- Ibuprofen Free
- Paraben Free

DYE

**FREE** 

Cherry Flavored
Dosage Cup Included

Package Contains One Bottle

8 FL OZ (237 mL)

### **DIRECTIONS:**

Step 1. Shake well before using

Step 2. Remove childprotective cap

Step 3. Pour your child's dose into the dosing cup

## **IMPORTANT**:

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

# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL **UNDER CAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Children's Tylenol® Oral Suspension.

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# **CHILDRENS PAIN AND FEVER**

acetaminophen suspension

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51316-097

**Route of Administration** 

ORAL

# **Active Ingredient/Active Moiety**

ingredient Name Dasis of Strength Strengt	Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN

160 mg in 5 mL

Inactive In	gredients
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ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CLYCEDIN (HNIII- PDC6A3COOY)	

GLYCERIN (UNII: PDC6A3C0OX)

HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)

WATER (UNII: 059QF0KO0R)

**SODIUM BENZOATE** (UNII: OJ245FE5EU)

**SORBITOL** (UNII: 506T60A25R) **SUCRALOSE** (UNII: 96K6UQ3ZD4) XANTHAN GUM (UNII: TTV12P4NEE)

#### **Product Characteristics**

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Color	white	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	

Contains

## **Packaging**

ш				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:51316- 097-19	1 in 1 CARTON	04/17/2024	
	1	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/17/2024	

# Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

# **Establishment**

Name	Address	ID/FEI	Business Operations

LNK International, Inc.	967626305	manufacture(51316-097), pack(51316-097)

Revised: 4/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED