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

CVS 44-079-Delisted

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.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this

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
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

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; FL OZ = fluid ounce
- 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

^{*}or as directed by a doctor

Other information

• each 5 mL contains: sodium 3 mg

- 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, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol, 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 added alcohol Aspirin & ibuprofen free No parabens

Strawberry Flavor

Dosage Cup Included

4 FL OZ (118 mL)

DIRECTIONS:

Step 1.

Shake well before using

Step 2.

Remove child-protective 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 Johnson & Johnson Corporation, 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:51316-079 ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	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 (UNII: K6790BS311)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316- 079-36	1 in 1 CARTON	07/18/2023	02/23/2026
1		118 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	07/18/2023	02/23/2026

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(51316-079), pack(51316-079)

Revised: 6/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED