

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

CVS 44-079

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

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.

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

♥CVS
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.

50844 ORG092207936

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Oral Suspension

Children's Pain & Fever

ACETAMINOPHEN
160 mg / 5 mL

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

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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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

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- new symptoms occur
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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.

Drug Facts (continued)

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Questions or comments? 1-800-426-9391

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50844 ORG092207936

B-0231-079-36-H
ORG092207936



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)

#693414

FPO 80%
UPC# 050428283899

X XXXXXX XXXXXX X

DIRECTIONS:



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before using



Step 2.
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protective cap



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CVS 44-079

CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51316-079

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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-079-36	1 in 1 CARTON	07/18/2023	
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	

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: 7/2023

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED