

## **PAIN RELIEF CHILDRENS- acetaminophen liquid**

### **Kroger Company**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Kroger Co. Children's Pain Relief Drug Facts**

#### **Active ingredient (in each 5 mL = 1 teaspoon)**

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

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 has ever had an allergic reaction to this product or any of its ingredients

#### **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. (1-800-222-1222)  
Quick medical attention is critical even if you do not notice any signs or symptoms.

## Directions

- this product does not contain directions or complete warnings for adult use
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than directed (see Liver warning)
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	1 tsp or 5 mL
36-47	4-5 years	1 1/2 tsp or 7.5 mL
48-59	6-8 years	2 tsp or 10 mL
60-71	9-10 years	2 1/2 tsp or 12.5 mL
72-95	11 years	3 tsp or 15 mL

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

## Other information

- each teaspoon contains: sodium 3 mg
- store at 20°-25°C (68°-77°F)
- do not use if printed neckband is broken or missing

## Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

**Questions or comments?**

1-800-632-6900

**Package/Label Principal Display Panel**

COMPARE TO active ingredient of CHILDREN'S TYLENOL® ORAL SUSPENSION

See side panel

For Ages 2 to 11

Children's Pain Relief

Acetaminophen

Oral Suspension

Pain Reliever/Fever Reducer

Dye-Free

Non-Staining

Alcohol Free, Aspirin Free, Ibuprofen Free, Gluten Free

No High Fructose Corn Syrup

Dosage Cup Included

Cherry Flavor

80 mg per ½ teaspoon

(160 mg per 5 ml)



For Ages 2 to 11

# Children's Pain Relief



**COMPARE TO**  
active ingredient of  
**CHILDREN'S  
TYLENOL® ORAL  
SUSPENSION**  
*\*See side panel*

NDC 30142-959-26  
For Ages 2 to 11

# Children's Pain Relief

**Acetaminophen  
Oral Suspension  
Pain Reliever/Fever Reducer**

**Dye-Free**

**Non-Staining**

- ▶ Alcohol Free, Aspirin Free, Ibuprofen Free, Gluten Free
- ▶ No High Fructose Corn Syrup



**COMPARE TO**  
active ingredient of  
**CHILDREN'S  
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**Our  
Pharmacists  
Recommend**

**4 FL OZ (118 ml)** 80 mg per 1/2 teaspoon  
(160 mg per 5 ml)

- ▶ Dosage Cup Included
- ▶ Cherry Flavor



**Our  
Pharmacists  
Recommend**

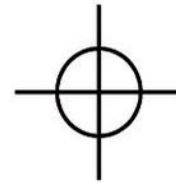
**4 FL OZ (118 ml)** 80 mg per 1/2 teaspoon  
(160 mg per 5 ml)



**LOT NO.**

**EXP.**

: 95926 45 C1





### Drug Facts

#### Active ingredient Purpose (in each 5 mL = 1 teaspoon)

Acetaminophen 160 mg...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

**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 has ever had an allergic reaction to this product or any of its ingredients

**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.

### Drug Facts (continued)

#### Directions

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#### Other information

- each teaspoon contains: sodium 3 mg
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**Inactive ingredients** anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

#### Questions or comments?

1-800-632-6900

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical even if you do not notice any signs or symptoms. ▶

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**GLUTEN FREE**

Distributed by The Kroger Co.  
Cincinnati, Ohio 45202

**QUALITY GUARANTEED**  
If you are not completely satisfied with this product, return it for a refund or replacement.  
Comments or questions?  
[www.Kroger.com](http://www.Kroger.com)



## PAIN RELIEF CHILDRENS

acetaminophen liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30 142-959
<b>Route of Administration</b>	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)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

SUCRALOSE (UNII: 96K6UQ3ZD4)

SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)

### Product Characteristics

<b>Color</b>	WHITE (opaque,viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-959-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/20/2012	

**Labeler** - Kroger Company (006999528)

Revised: 10/2012

Kroger Company