# SHOPRITE CHILDRENS ACETAMINOPHEN- acetaminophen suspension Wakefern Food Corporation

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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# ShopRite Children's Acetaminophen Drug Facts

# Active ingredient (in each 5 mL)

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

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 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

# 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 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 (see overdose warning)
- shake well before using
- 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	2-3 years	5 mL	
36-47	4-5 years	7.5 mL	
48-59	6-8 years	10 mL	
60-71	9-10 years	12.5 mL	
72-95	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

- each 5 mL contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing
- see bottom panel for lot number and expiration date

# **Inactive ingredients**

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

## Questions or comments?

1-800-SHOPRITE

# **Principal Display Panel**

Compare to: Active Ingredient in Children's Tylenol® Oral Suspension

Children's

**AGES 2-11 YEARS** 

**ACETAMINOPHEN** 

160 mg PER 5 mL

Pain Reliever – Fever Reducer

Suspension Liquid

PAIN & FEVER

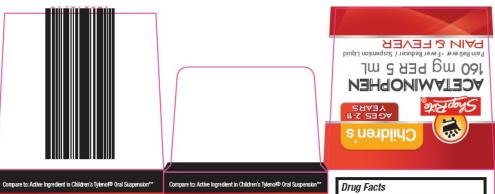
Aspirin Free

Ibuprofen Free

Alcohol Free

Cherry flavor

4 FL OZ (118 mL)





# **ACETAMINOPHEN** 160 mg PER 5 mL

Pain Reliever • Fever Reducer Suspension Liquid

#### PAIN & FEVER

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Children's

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Pain Reliever • Fever Reducer Suspension Liquid

#### PAIN & FEVER

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Cherry

4 FL OZ (118 mL)

Active ingredient (in each 5 mL)

Purpose

etaminophen 160 mg

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

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

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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

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.
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#### Drug Facts (continued)

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- or missing

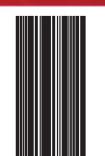
  see bottom panel for lot number and expiration date

Inactive Ingredients anhydrous citic acid, butylgraben, calcium sulfate, carragenan, FD&C ed #4.0, flavo, glycerin, high rucbes com syrup, hydroxyethyl cellulose socium, propylene glycol, purified water, sodium berzoate, sorbitol sulfution, purified water, sodium berzoate, sorbitol sulfution, tribasic sodium phosphate

#### Questions or comments?

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

Distributed By: Wakefern Food Corp. 5000 Riverside Drive Keasbey, NJ 08832 ©2015





LOT NO.

EXP.

: 17526 AB CS

# SHOPRITE CHILDRENS ACETAMINOPHEN

acetaminophen suspension

# **Product Information**

HUMAN OTC DRUG NDC:41190-175 Product Type Item Code (Source)

ORAL Route of Administration

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CALCIUM SULFATE (UNII: WAT0 DDB 505)		
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30A6X)		

Product Characteristics			
Color	RED (opaque)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:41190-175-26	1 in 1 CARTON	08/14/2013	
1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/14/2013	

# **Labeler** - Wakefern Food Corporation (069722418)

Revised: 12/2018 Wakefern Food Corporation