# TOPCARE CHILDRENS PAIN AND FEVER- acetaminophen suspension Topco Associates LLC

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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# Topco Associates LLC. Children's Pain & Fever 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

# **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?

1-888-423-0139

# Package/Label Principal Display Panel

COMPARE TO CHILDREN'S TYLENOL® ORAL SUSPENSION ACTIVE INGREDIENT

children's Pain & Fever

**ORAL SUSPENSION** 

ACETAMINOPHEN, 160 mg per 5 mL

PAIN RELIEVER • FEVER REDUCER

OUR PHARMACISTS RECOMMEND

**DYE-FREE** 

Aspirin Free

Ibuprofen Free

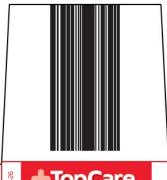
Alcohol Free

Ages 2 to 11 Years

**DYE-FREE** 

**CHERRY FLAVOR** 

4 FL OZ (118 mL)





information

Pain & Fever

**<b>◆TopCare**。



COMPARE TO CHILDREN'S TYLENOL®
ORAL SUSPENSION ACTIVE INGREDIENT\*\*

# children's Pain &

**ORAL SUSPENSION** 

ACETAMINOPHEN, 160 mg per 5 mL PAIN RELIEVER . FEVER REDUCER

### DYE-FREE

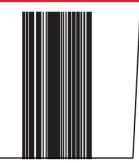
- Aspirin Free
- Ibuprofen Free
- Alcohol Free





Ages z

11 Years





# children's Pain &

**ORAL SUSPENSION** ACETAMINOPHEN, 160 mg per 5 mL PAIN RELIEVER . FEVER REDUCER

#### DYE-FREE

DIRECTIONS: STEP 1. Shake well before using



STEP 2. Remove child protective



STEP 3. Squeeze your child's dose into the dosing cup



#### IMPORTANT:

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

#### Drug Facts

Active ingredient (in each 5 mL) cetaminophen 160 mg.

Purpose

### Uses temporarily:

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

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with other drugs containing acetaminophen
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reactions. Symptoms may include:

skin reddering blisters area
fa skin reaction occurs, stop use and seek medical help

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- 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

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■ new symptoms occur
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#### Drug Facts (continued)

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#### Other information

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   store at 20-25°C (68-77°F)
   do not use if printed neckband is broken or missing

#### Inactive ingredients

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

#### Questions or comments? 1-888-423-0139

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



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# TOPCARE CHILDRENS PAIN AND FEVER

acetaminophen suspension

#### **Product Information**

NDC:36800-959 Product Type HUMAN OTC DRUG 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)		
CALCIUM SULFATE (UNII: WAT0 DDB505)		
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
GLYCERIN (UNII: PDC6A3C0OX)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8 IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
SO DIUM PHO SPHATE, TRIBASIC (UNII: A752Q30A6X)		

Product Characteristics		
Color	WHITE (opaque, viscous)	Score
Shape		Size
Flavor	CHERRY	Imprint Code
Contains		

	Packaging			
2	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	NDC:36800-959-26	1 in 1 CARTON	02/27/2012	
	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	02/27/2012	

# Labeler - Topco Associates LLC (006935977)

Revised: 11/2018 Topco Associates LLC