# EQUATE CHILDRENS PAIN AND FEVER- acetaminophen suspension Wal-Mart Stores Inc

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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# Wal-Mart 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?

1-888-287-1915

# Package/Label Principal Display Panel

Compare to Children's Tylenol® Oral Suspension active ingredient

children's

PAIN & FEVER

Acetaminophen 160 mg per 5mL

Oral Suspension

Pain Reliever/Fever Reducer

AGES 2 to 11 YEARS

Fast, effective relief of children's pain and fever

Alcohol Free

Aspirin Free

Ibuprofen Free

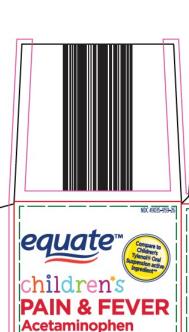
No High Fructose Corn Syrup

Dye Free

Cherry Flavored

4 FL OZ (118 mL)

Dosage Cup Included



160 mg per 5 mL Oral Suspension

Fast, effective relief of

■ Alcohol Free

 Aspirin Free Ibuprofen Free

**Dye Free** 

Cherry

Flavored

No High Fructos Corn Syrup

children's pain and fever

Pain Reliever/Fever Reducer

AGES 2 to 11 YEARS

### DIRECTIONS:

STEP 1. Shake well before using



STEP 2. Remove child protective cap



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) Acetaminophen 160 mg. Purpose

.....Pain reliever/fever reduce

- Uses temporarily:

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   relieves minor aches and pains due to:
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   flu headache
   sore throat
   toothache

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Dye Free • Cherry Flavored AGES 2 to 11 YEARS

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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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#### Drug Facts (continued)

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Questions or comments? 1-888-287-1915

# DISTRIBUTED BY: Wallmart Inc.,

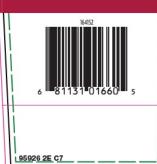
Bentonville, AR 72716

\*\*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Tylenol®.





Satisfaction guaranteed – Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.



# EQUATE CHILDRENS PAIN AND FEVER

acetaminophen suspension

# **Product Information** HUMAN OTC DRUG NDC:49035-959 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)		
CALCIUM SULFATE (UNII: WAT0 DDB505)		
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
GLYCERIN (UNII: PDC6A3C0OX)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS311)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
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				
	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
	1 NDC:49035-959-26	1 in 1 CARTON	0 1/24/20 12		
l	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	0 1/24/20 12	

# Labeler - Wal-Mart Stores Inc (051957769)

Revised: 10/2018 Wal-Mart Stores Inc