

ACETAMINOPHEN- acetaminophen suspension
Healthlife of USA

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.

Children's Acetaminophen Oral Suspension
Pain Reliever/ Fever Reducer

Drug Facts

Active ingredient (in each 5mL)

Acetaminophen 160mg

Purpose

Fever reducer/ pain reliever

Uses

Temporarily:

1. reduces fever
2. 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.

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.

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

When using this product do not exceed recommended dose

(See overdose warning)

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

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. Quick 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
- mL=mililiter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- fill to dose level. Do not use any other dosing device
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- rinse the dosing device after each use
- do not give more than 5 times in 24 hours
- shake well before use
- do not give moer than directed.

Weight (lb)	Age (Year)	Dose (mL)*
Under 24	Under 2 years	Ask a doctor
24-35	2-3 years	5mL
36-47	4-5 years	7.5mL
48-59	6-8 years	10mL
60-71	9-10 years	12.5mL
72-95	11 years	15mL

* or as directed by a doctor

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

Other information

- Store between 15°-30°C (59°-86°F)
- Protect from freezing
- Protect from light

Inactive ingredients

Acesulfame Potassium, Avicel, Butyl paraben, citric acid, FD&C Red #33, FD&C Blue #1, Glycerin, High fructose corn syrup, Nat grape flavor, polysorbate 80, propylene glycol, sodium benzoate, sorbitol, sucralose, Prosweet N and A, Purified water, xanthan gum

Questions or comments?

Call 1-844-832-1138

**Children's Acetaminophen Oral Suspension
Pain Reliever/ Fever Reducer**

Distributed by:

Healthlife of USA

1600 Hart Street,

Rahway, NJ 07065

www.healthlifeofusa.com



ACETAMINOPHEN			
acetaminophen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-624
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Acetaminophen (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	Acetaminophen	160 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-624-17	1 in 1 CARTON	01/10/2018	
1		15 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	01/10/2018	

Labeler - Healthlife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Kingston Pharma LLC		080386521	manufacture(69517-624)

Revised: 1/2018

Healthlife of USA