

CHILDRENS ACETAMINOPHEN- acetaminophen suspension
Cardinal Health 107, LLC

Children's Acetaminophen Oral Suspension
Ibuprofen Free/Alcohol Free/Aspirin Free

Drug Facts

Active ingredient
(in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily:

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

Warnings

Liver warning: This product contains 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 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 the 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 the 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 for adults as well as children even if you do not notice any sign or symptoms

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not take more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lbs)	Age (yr)	Dose (mL) *
Under 24	Under 2	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

* or as directed by a doctor

Other information

- each 5 mL contains: sodium 2 mg
- Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- protect from freezing
- a red, berry flavored suspension supplied in the following oral dosage form:

Overbagged with 5 Unit-Dose Cups per bag, NDC 55154-5787-5

Inactive ingredients

Acesulfame K, butylparaben, citric acid, FD&C Red No. 40, flavoring, glycerin, high fructose corn syrup, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, veegum and xanthan gum.

Questions or comments?

Call 1-800-845-8210.

MANUFACTURED BY

Pharmaceutical Associates, Inc.

Greenville, SC 29605

www.paipharma.com

Distributed By:

Cardinal Health

Dublin, OH 43017

L55345731223

R09/20

PRINCIPAL DISPLAY PANEL - 5 mL Cup

Children's Acetaminophen Oral Suspension

160 mg per 5 mL

5 Unit-Dose Cups



W120

NDC 55154-5787-5

CHILDREN'S ACETAMINOPHEN

ORAL SUSPENSION

160 mg per 5 mL

5 UNIT-DOSE CUPS

Delivers 5 mL

Pain Reliever-Fever Reducer

Ibuprofen Free / Alcohol Free / Aspirin Free

Usual Dosage: See product insert for prescribing information, precautions and warnings.

STORAGE: Store at 20° to 25° C (68° to 77° F)

[See USP Controlled Room Temperature]

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only.

Keep this and all drugs out of the reach of children.

SHAKE WELL BEFORE USING

Pharmaceutical Associates, Inc.

201 Delaware Street

Greenville, SC 29605

(800) 845-8210

www.paipharma.com

DURA-DOSE®

Distributed by Cardinal Health

Dublin, OH 43017

L55345731223

Lot: Exp:

CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-5787(NDC:0121-1781)
Route of Administration	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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SORBITOL (UNII: 506T60A25R)				
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	red	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5787-5	5 in 1 BAG	09/17/2007	
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M013	09/17/2007	

Labeler - Cardinal Health 107, LLC (118546603)