

**CHILDRENS ACETAMINOPHEN- childrens acetaminophen suspension  
Pharmaceutical Associates, 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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**Children's Acetaminophen Oral Suspension**

**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 warnings**

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 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 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

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
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

\*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)
- grape flavored suspension supplied in the following oral dosage forms:

NDC 0121-0946-05: 5 mL unit dose cup, in a tray of ten cups.

**Inactive ingredients**

acesulfame K, butylparaben, citric acid, 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.

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

\*\*\*Gluten Free

MANUFACTURED BY

Pharmaceutical Associates, Inc.

Greenville, SC 29605

[www.paipharma.com](http://www.paipharma.com)

R06/21

**PRINCIPAL DISPLAY PANEL - 5 mL Cup Label**

Delivers 5 mL

NDC 0121-0946-05

**Children's Acetaminophen Oral Suspension**

**160 mg per 5 mL**

**DYE FREE/GRAPE FLAVOR**

**Ibuprofen Free/Alcohol Free/Aspirin Free**

Package Not Child-Resistant

Rx ONLY

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

A0946050621

Delivers **5 mL**  
NDC 0121-0946-05

**CHILDREN'S  
ACETAMINOPHEN  
ORAL SUSPENSION  
160 mg per 5 mL**

**DYE FREE/GRAPE FLAVOR**  
*Ibuprofen Free/Alcohol Free/Aspirin Free*  
Pain Reliever-Fever Reducer  
**SHAKE WELL BEFORE USING**

Made in USA  
A094605094601



(01) 0 0301210 94605 9

**Package Not Child-Resistant**  
Pharmaceutical Associates, Inc.  
Greenville, SC 29605

**SEE INSERT**

## CHILDRENS ACETAMINOPHEN

childrens acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0121-0946
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white (to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0946-30	3 in 1 CASE	09/07/2021	
1		10 in 1 TRAY		
1	NDC:0121-0946-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0946-00	10 in 1 CASE	09/07/2021	
2		10 in 1 TRAY		
2	NDC:0121-0946-05	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 not final	part343	09/07/2021	

**Labeler** - Pharmaceutical Associates, Inc. (044940096)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0946) , label(0121-0946)