

**CHILDRENS ACETAMINOPHEN ORAL SUSPENSION- acetaminophen suspension  
PAI Holdings, LLC**

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**Childrens Acetaminophen Oral Suspension**

**Drug Facts**

**Active ingredient**

(in each 5 mL)  
Acetaminophen 160 mg

**Purpose**

Acetaminophen  
160 mg.....Pain reliever/fever reducer

**Uses temporarily:**

- reduces fever
- 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 non-prescription). 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:**

- 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 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

**Attention:** For Single-Dose Cups, the entire dose should be taken.

**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

\*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 form:

NDC 0121-0966-05: 5 mL unit dose cup, in a tray of ten cups.

NDC 0121-0966-94: Case contains 30 unit dose cups of 5 mL (0121-0966-05) packaged in 3 trays of 10 unit dose cups each.

NDC 0121-0966-00: Case contains 100 unit dose cups of 5 mL (0121-0966-05) packaged in 10 trays of 10 unit dose cups each.

**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.

**MANUFACTURED BY:**

Pharmaceutical Associates, Inc.

Greenville, SC 29605

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

R01/22

**Principal Display Panel**

Delivers **5 mL**

NDC 0121-0966-05

DYE FREE/GRAPE FLAVOR

**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

**Package Not Child-Resistant**

Pharmaceutical Associates, Inc.

SEE INSERT



## CHILDRENS ACETAMINOPHEN ORAL SUSPENSION

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0121-0966
<b>Route of Administration</b>	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
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

**SORBITOL SOLUTION** (UNII: 8KW3E207O2)

**XANTHAN GUM** (UNII: TTV12P4NEE)

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0966-94	3 in 1 CASE	03/09/2022	
1		10 in 1 TRAY		
1	NDC:0121-0966-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0966-00	10 in 1 CASE	03/09/2022	
2		10 in 1 TRAY		
2	NDC:0121-0966-05	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 Drug	M013	03/09/2022	

**Labeler - PAI Holdings, LLC (044940096)**

### Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	label(0121-0966) , manufacture(0121-0966)

Revised: 12/2023

PAI Holdings, LLC