DYE FREE CHILDRENS ACETAMINOPHEN- acetaminophen suspension
PAI Holdings, LLC dba PAI Pharma

Dye Free Childrens Acetaminophen

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

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

DYE FREE CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0966
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**
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

Color	white (to off-white appearance)	**Score**	
Shape		**Size**	
Flavor	GRAPE (grape flavor)	**Imprint Code**	
Contains			

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 dba PAI Pharma (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)