ACETAMINOPHEN- acetaminophen solution
PAI Holdings, LLC dba PAI Pharma

Acetaminophen Oral Solution USP

Alcohol Free/Dye Free/Sugar Free
Grape Flavored

Active ingredient
(in each 5 mL)

Acetaminophen 160 mg

Purposes

Pain reliever/fever reducer

Uses

• for the temporary relief of minor aches and pains due to
- headache
- muscular aches
- backache
- sore throat
- flu
- the common cold
- toothache
- premenstrual and menstrual cramps

• for the minor pain from arthritis
• and to reduce fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if
- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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 you are allergic to aetaminophen or any of the inactive ingredients of this product

Ask a doctor before use if the user

- has liver disease
- is a child with pain of arthritis

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- adult's pain gets worse or lasts more than 10 days
- child's pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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 signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**
- **dose product from the single dose cup the product is packaged in**
- **mL=milliliter**

age	dose

adults and children 12 years of age and over	20 mL (640 mg) every 4 to 6 hours not to exceed 6 doses in a 24-hour period
children 6 to under 12 years of age	10 mL (320 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children 4 to under 6 years of age	7.5 mL (240 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children 2 to under 4 years of age	5 mL (160 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children under 2 years of age	consult a doctor

Other information

■ Each 5 mL contains: **sodium 6 mg**

■ store at 20° to 25°C (68° to 77°F)

Inactive ingredients anhydrous citric acid, edetate disodium, flavor, glycerin, polyethylene glycol 400, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose, trisodium citrate dihydrate

Questions or comments?

Call 1-800-845-8210. You may also report serious side effects to this phone number.

Distributed by:

PAI Pharma
Greenville,SC 29605
www.paipharma.com
R05/25

PRINCIPAL DISPLAY PANEL - 5 mL Cup

Delivers **5 mL**

NDC 0121-1047-05

Acetaminophen
Oral Solution USP
160 mg/5 mL

Pain Reliever/Fever Reducer

Alcohol Free/Dye Free/Sugar Free
Grape Flavored

Package Not Child-Resistant

Dist. by: PAI Pharma
GREENVILLE, SC 29605

See insert for drug facts

ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1047
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**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	

SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1047-00	10 in 1 CASE	12/09/2025	
1		10 in 1 TRAY		
1	NDC:0121-1047-05	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	12/09/2025	

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	manufacture(0121-1047)

Revised: 12/2025 PAI Holdings, LLC dba PAI Pharma