ACETAMINOPHEN- acetaminophen solution
PAI Holdings, LLC dba PAI Pharma

Acetaminophen Oral Solution USP

Alcohol Free

Active ingredient
(in each 5 mL teaspoonful)

ACETAMINOPHEN 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps

temporarily reduces 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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients of this product

Ask a doctor before use if the user has liver disease

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

Stop use and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

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)**

age	dose
adults and children 12 years of age and over	20.3 mL (650 mg) every 4 to 6 hours not to exceed 6 doses in a 24-hour period
children 6 to under 12 years of age	10.15 mL (325 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 2 mg

■ store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]

■ keep tightly closed ■ protect from light

■ a red, cherry flavored solution supplied in the following oral dosage forms:

NDC 0121-0657-05: 5 mL unit dose cup

NDC 0121-0657-00: Case contains 100 unit dose cups of 5 mL (0121-0657-05) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-1314-11: 10.15 mL unit dose cup

NDC 0121-1314-00: Case contains 100 unit dose cups of 10.15 mL (0121-1314-11) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-1971-21: 20.3 mL unit dose cup

NDC 0121-1971-00: Case contains 100 unit dose cups of 20.3 mL (0121-1971-21) packaged in 10 trays of 10 unit dose cups each.

Inactive ingredients:

Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol and sucrose.

Questions or comments?

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

MANUFACTURED BY:

Pharmaceutical Associates, Inc.

Greenville, SC 29605

www.paipharma.com

R10/20

PRINCIPAL DISPLAY PANEL - 5 mL Cup

Delivers **5 mL**

NDC 0121-0657-05

Acetaminophen Oral Solution USP

160 mg/5 mL

ALCOHOL FREE

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

SEE INSERT

F0657051020

PRINCIPAL DISPLAY PANEL - 10 mL Cup

Delivers **10.15 mL**

NDC 0121-1314-11

Acetaminophen Oral Solution USP

325 mg/10.15 mL

ALCOHOL FREE

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT

F0657111020

PRINCIPAL DISPLAY PANEL - 20.3 mL Cup

Delivers **20.3 mL**

NDC 0121-1971-21

Acetaminophen Oral Solution USP

650 mg/20.3 mL

ALCOHOL FREE

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT

F0657211020

ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0657

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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red (clear, red liquid)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0657-00	10 in 1 CASE	08/01/2007	
1		10 in 1 TRAY		
1	NDC:0121-0657-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0657-11	10 in 1 CASE	08/01/2007	
2		10 in 1 TRAY		
2		10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0121-0657-21	10 in 1 CASE	08/01/2007	
3		10 in 1 TRAY		
3		20.3 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	08/01/2007	

ACETAMINOPHEN

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1314
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10.15 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1314-00	10 in 1 CASE	08/01/2007	
1		10 in 1 TRAY		
1	NDC:0121-1314-11	10.15 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	08/01/2007	

ACETAMINOPHEN

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1971
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20.3 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0121-			

1	NDC:0121-1971-00	10 in 1 CASE	08/01/2007	
1		10 in 1 TRAY		
1	NDC:0121-1971-21	20.3 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	08/01/2007	

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(0121-0657, 0121-1314, 0121-1971)

Revised: 8/2024 PAI Holdings, LLC dba PAI Pharma