ACETAMINOPHEN- 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.

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 warning

This product contains acetaminophen. Severe liver damage may occur if
- adult takes more than 4,000 mg of acetaminophen in 24 hours
- 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 have ever had an allergic reaction to this product or any of its ingredients

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 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 10 days (for adults) or 5 days (for children)
- 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.

- do not give this product to children for the pain of arthritis unless directed by a doctor

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

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 for children even if you do not notice any signs or symptoms.

Directions

- **Use as directed per healthcare professional.**
- **do not take more than directed (see overdose warning)**
- **shake well before using**
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- repeat dose every 4 hours while symptoms last
- do not take more than 5 times in 24 hours

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
Over 96	adults and children 12 years and over	20 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)

Inactive ingredients

acesulfame potassium, butylparaben, citric acid anhydrous, flavoring, glycerin, high fructose corn syrup, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, and xanthan gum.

Alcohol Free, Aspirin Free, Gluten Free, Ibuprofen Free

How Supplied

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

NDC 0121-0941-05: 5 mL unit dose cup, in a tray of ten cups.

NDC 0121-1882-11: 10.15 mL unit dose cup, in a tray of ten cups.

NDC 0121-2823-21: 20.3 mL unit dose cup, in a tray of ten cups.

Call 1-800-845-8210.

MANUFACTURED BY

Pharmaceutical Associates, Inc.

Greenville, SC 29860

www.paipharma.com

PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

NDC 0121-0941-05

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.

Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 10.15 mL Cup Label

NDC 0121-1882-11

ACETAMINOPHEN ORAL SUSPENSION

325 mg per 10.15 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.

Greenville, SC 29605

PRINCIPAL DISPLAY PANEL - 20.3 mL Cup Label

NDC 0121-2823-21

ACETAMINOPHEN ORAL SUSPENSION

650 mg per 20.3 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.

Greenville, SC 29605

ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0941
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
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)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0941-94	3 in 1 CASE	09/03/2021	
1		10 in 1 TRAY		
1	NDC:0121-0941-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0941-00	10 in 1 CASE	09/03/2021	
2		10 in 1 TRAY		
2	NDC:0121-0941-05	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	09/03/2021	

ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1882
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
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)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-	2 in 1 CASE	09/03/2021	

1	1882-94	3 in 1 CASE	09/03/2021	
1		10 in 1 TRAY		
1	NDC:0121-1882-11	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-1882-00	10 in 1 CASE	09/03/2021	
2		10 in 1 TRAY		
2	NDC:0121-1882-11	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 not final	part343	09/03/2021	

ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-2823
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
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)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-2823-94	3 in 1 CASE	09/03/2021	
1		10 in 1 TRAY		
1	NDC:0121-2823-21	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 not final	part343	09/03/2021	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Registrant - Pharmaceutical Associates, Inc. (097630693)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0941, 0121-1882, 0121-2823) , label(0121-0941, 0121-1882, 0121-2823)

Revised: 12/2021 Pharmaceutical Associates, Inc.