ACETAMINOPHEN- acetaminophen suspension Precision Dose, Inc.

ACETAMINOPHEN ORAL SUSPENSION

Grape Flavor 80 mg/2.5 mL 160 mg/5 mL 325 mg/10.15 mL 650 mg/20.3 mL *For Hospital Use Only*

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 your child has ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if your child 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 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 give 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 3 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-800-397-9228

Alcohol Free, Aspirin Free, Gluten Free, Ibuprofen Free

How Supplied

NDC 68094-130-58 2.5 mL per unit dose syringe Fifty (50) syringes per shipper

NDC 68094-231-58 5 mL per unit dose syringe Fifty (50) syringes per shipper

NDC 68094-231-61 5 mL per unit dose cup One hundred (100) cups per shipper

NDC 68094-231-62 5 mL per unit dose cup Thirty (30) cups per shipper

NDC 68094-330-61

10.15 mL per unit dose cup One hundred (100) cups per shipper

NDC 68094-330-62 10.15 mL per unit dose cup Thirty (30) cups per shipper

NDC 68094-030-62 20.3 mL per unit dose cup Thirty (30) cups per shipper

Packaged By **Precision Dose, Inc.** South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email druginfo@precisiondose.com

LI1263 Rev. 04/23

PRINCIPAL DISPLAY PANEL - 10.15 mL Cup Label

NDC 68094-330-59

PrecisionDose™

ACETAMINOPHEN Oral Suspension 325 mg/10.15 mL

Delivers 10.15 mL Shake Well Each 5 mL contains Sodium 3 mg Alcohol Free Aspirin Free Gluten Free Ibuprofen Free

Hospital Use Only Store at 20°-25°C (68°-77°F) Pkg. By: Precision Dose, Inc. South Beloit, IL 61080 1303 R1



ACETAMINOPHEN						
acetaminophen suspension						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sour	ce)	NDC:68094-330(N	NDC:0113	3-0212)
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
Ingredient Name Basis of Strength				Stre	ngth	
Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)			Aceta	minophen	160 mg	in 5 mL
Inactive Ingredients						
Ingredient Name					Str	ength
anhydrous citric acid (UNII: XF417D3PSL)						
butylparaben (UNII: 3QPI1U3FV8)						
calcium sulfate, unspecified form (UNII: WATODDB505)						
carrageenan (UNII: 5C69YCD2YJ)						
D&C red no. 33 (UNII: 9DBA0SBB0L)						
FD&C blue no. 1 (UNII: H3R47K3T	BD)					
glycerin (UNII: PDC6A3C0OX)						

high fructose corn syrup (UNII: XY6UN3QB6S)	
microcrystalline cellulose (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sodium phosphate, tribasic (UNII: A752Q30A6X)	

Product Characteristics

Color	PURPLE (viscous)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:68094- 330-62	3 in 1 CASE	01/15/2020			
1		10 in 1 TRAY				
1	NDC:68094- 330-59 10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product					
2	NDC:68094- 330-61	10 in 1 CASE	01/15/2020			
2		10 in 1 TRAY				
2	NDC:68094- 330-59	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		
ОТ	TC Monograph Di	rug M013	01/15/2020			

Labeler - Precision Dose, Inc. (035886746)

Establishment				
Name	Address	ID/FEI	Business Operations	
Precision Dose, Inc.		035886746	REPACK(68094-330)	
Establishment				

Establishment						
Name	Address	ID/FEI	Business Operations			
L Perrigo Company		006013346	MANUFACTURE(68094-330)			