ACETAMINOPHEN- acetaminophen suspension
Precision Dose, Inc.
Reference Label Set Id: e1d4f562-433c-4344-9b77-1a7c731d1be5

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 - 5 mL Cup Label

NDC 68094-231-59

PrecisionDose™

ACETAMINOPHEN
Oral Suspension
160 mg/5 mL

Pkg: Precision Dose, Inc., S. Beloit, IL 61080

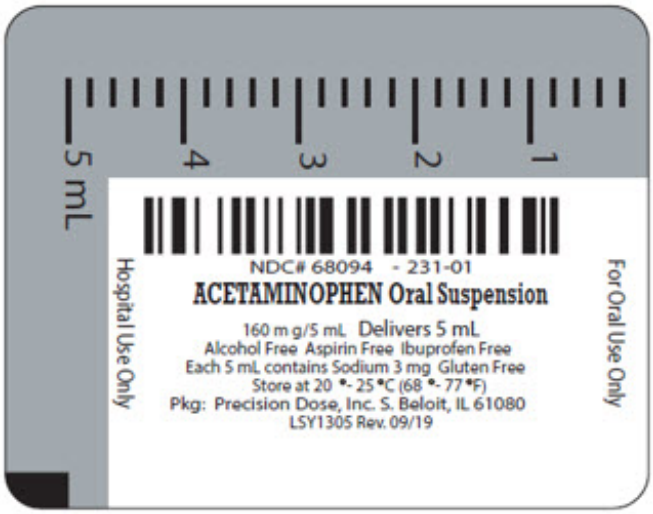
PRINCIPAL DISPLAY PANEL - 5 mL Syringe Label

Hospital Use Only

NDC# 68094 - 231-01
ACETAMINOPHEN Oral Suspension

160 m g/5 mL Delivers 5 mL
Alcohol Free Aspirin Free Ibuprofen Free
Each 5 mL contains Sodium 3 mg Gluten Free
Store at 20 °- 25 °C (68°-77 °F)
Pkg: Precision Dose, Inc. S. Beloit, IL 61080
LSY1305 Rev. 09/19

For Oral Use Only



ACETAMINOPHEN

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68094-231(NDC:0113-0212)
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)	
butylparaben (UNII: 3QPI1U3FV8)	
calcium sulfate, unspecified form (UNII: WAT0DDB505)	
carrageenan (UNII: 5C69YCD2YJ)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
glycerin (UNII: PDC6A3C0OX)	
high fructose corn syrup (UNII: XY6UN3QB6S)	
microcrystalline cellulose (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-231-62	3 in 1 CASE	04/01/2020	
1		10 in 1 TRAY		
1	NDC:68094-231-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:68094-231-61	10 in 1 CASE	04/01/2020	
2		10 in 1 TRAY		
2	NDC:68094-231-59	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:68094-231-58	5 in 1 CASE	07/31/2023	
3		10 in 1 BAG		
3	NDC:68094-231-01	5 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M013	04/01/2020	

Labeler - Precision Dose, Inc. (035886746)

Establishment

Name	Address	ID/FEI	Business Operations
Precision Dose, Inc.		035886746	REPACK(68094-231)

Revised: 1/2024 Precision Dose, Inc.