

## **ACETAMINOPHEN- acetaminophen suspension**

**Precision Dose, Inc.**

**Reference Label Set Id: e1d4f562-433c-4344-9b77-1a7c731d1be5**

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### **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 Institutional 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 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 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

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
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**

NOC 68094-042-58

2.5 ml per unit dose ENFit syringe

Fifty (50) syringes per shipper

NOC 68094-038-58

5 ml per unit dose ENFit syringe

Fifty (50) syringes per shipper

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](mailto:druginfo@precisiondose.com)

LI1650 Rev. 03/24

### **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

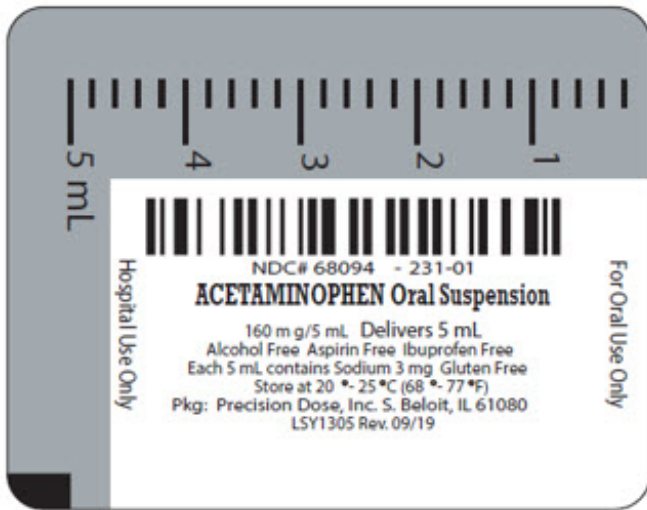
Each 5 mL contains Sodium 3 mg Gluten Free

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68094-231(NDC:0113-0212)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Acetaminophen</b> (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	Acetaminophen	160 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>butylparaben</b> (UNII: 3QPI1U3FV8)	
<b>calcium sulfate, unspecified form</b> (UNII: WAT0DDB505)	
<b>carrageenan</b> (UNII: 5C69YCD2YJ)	
<b>D&amp;C red no. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C blue no. 1</b> (UNII: H3R47K3TBD)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>high fructose corn syrup</b> (UNII: XY6UN3QB6S)	
<b>microcrystalline cellulose</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>sodium phosphate, tribasic</b> (UNII: A752Q30A6X)	

## Product Characteristics

<b>Color</b>	PURPLE (viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

## 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: 7/2024

Precision Dose, Inc.