

ACETAMINOPHEN- acetaminophen suspension

Precision Dose, Inc.

Reference Label Set Id: 554a7381-7f9a-4782-916a-10f9bc44b4f6

Reference Label Set Id: d3d32de6-9272-43c9-9b31-bd1f45c55a8d

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

LI1650 Rev. 10/24

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

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 68094-042-58

2.5 mL per unit dose ENFit syringe

Fifty (50) syringes per shipper

NDC 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

LI1650 Rev. 10/24

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

ACETAMINOPHEN ORAL SUSPENSION

160 mg / 5 mL

Delivers 5 mL

Store at 20-25°C (68-77°F)

Hospital Use Only • Alcohol Free

Aspirin Free • Gluten Free • Ibuprofen Free

For Oral Use Only

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

LSY1609 Rev. 04/23



NDC 68094-231-01

ACETAMINOPHEN ORAL SUSPENSION

160 mg / 5 mL Delivers 5 mL

Store at 20-25°C (68-77°F)

Hospital Use Only • Alcohol Free
Aspirin Free • Gluten Free • Ibuprofen Free

For Oral Use Only

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

3 80 06



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
U1650 Rev. 10/24

Drug Facts

Active ingredient *Purpose*
(in each 5 mL)
Acetaminophen 160 mg.....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.

Drug Facts (continued)

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 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 68094-042-58
2.5 mL per unit dose ENFit syringe
Fifty (50) syringes per shipper

NDC 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

U1650 Rev. 10/24

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



PRINCIPAL DISPLAY PANEL - 20.3 mL Cup Label

NDC 68094-030-59

PrecisionDose™

ACETAMINOPHEN

Oral Suspension

650 mg/20.3 mL

Delivers 20.3 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.

S. Beloit, IL 61080

1262 R1



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	

ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-330(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:68094-330-62	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
OTC Monograph Drug	M013	01/15/2020	

ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-030(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)	
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
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1	NDC:68094-030-62	3 in 1 CASE	09/06/2019	
1		10 in 1 TRAY		
1	NDC:68094-030-59	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	09/06/2019	

Labeler - Precision Dose, Inc. (035886746)

Establishment

Name	Address	ID/FEI	Business Operations
Precision Dose, Inc.		035886746	REPACK(68094-231, 68094-330, 68094-030)

Establishment

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

Revised: 8/2025

Precision Dose, Inc.