

ACETAMINOPHEN- acetaminophen solution
VistaPharm, 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 Solution, USP
325 mg/10.15 mL

Active ingredient (in each 10.15 mL)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscle aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 mg in 24 hours
- with other drugs containing acetaminophen
- 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.

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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- 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.

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

- **do not take more than directed (see overdose warning)**
- do not take more than 8 doses in any 24-hour period
- dose as follows or as directed by doctor
- take only with dosing cup provided
- adults and children 12 years of age and older: 10.15 mL (325 mg) every 3 - 4 hours
- children under 12 years of age: ask a doctor

Other information

- each 10.15 mL contains: **sodium 16 mg**
- store at 20 -25°C (68 -77°F)
- do not use if foil on cup is missing or torn

Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD& C red no. 40, flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, sodium saccharin

Questions or comments?

Call 1-888-655-1505

How Supplied

NDC 66689-055-01: 10.15 mL unit-dose cup

NDC 66689-055-99: Case contains 100 unit-dose cups of 10.15 mL (NDC 66689-055-01), packaged in 10 trays of 10 unit-dose cups each.

Distributed by:

VistaPharm Inc.
Largo, FL 33771, USA
VP2511
10/2019

Principal Display Panel - 10.15 mL Lidding Label

ACETAMINOPHEN Oral Solution, USP

325 mg per 10.15 mL

[160 mg/5 mL]

Alcohol-Free

Delivers 325 mg [10.15 mL]

Store at 20°-25°C (68°-77°F); [see USP CRT conditions].

Distributed by:

VistaPharm, Inc.
Largo, FL 33771, USA
NDC 66689-055-01
VP2155R2
02/18

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VP2155R2
02/18



NDC 66689-055-01

ACETAMINOPHEN

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66689-055
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)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66689-055-99	10 in 1 CASE	11/22/2019	
1		10 in 1 TRAY		
1	NDC:66689-055-01	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	11/22/2019	

Labeler - VistaPharm, Inc. (116743084)

Revised: 12/2019

VistaPharm, Inc.