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
650 mg/20.3 mL

Drug Facts

Active ingredient (in each 20.3 mL)

Acetaminophen 650 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 4 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: 20.3 mL (650 mg) in dosing cup every 6 hours

■ children under 12 years of age: ask a doctor

Other information

■ each 20.3 mL contains: **sodium 32 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 66689-056-01: 20.3 mL unit-dose cup

NDC 66689-056-99: Case contains 100 unit- dose cups of 20.3 mL (NDC 66689-056-01), packaged in 10 trays of 10 unit-dose cups each.

Distributed by:

VistaPharm Inc.

Largo, FL 33771, USA

VP2512

10/2019

Principal Display Panel - 20.3 mL Lidding Label

ACETAMINOPHEN Oral Solution, USP

650 mg per 20.3 mL

[160 mg/5 mL]

Alcohol-Free

Delivers 650 mg [20.3 mL]

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

Distributed by:

VistaPharm, Inc.
Largo, FL 33771, USA

NDC 66689-056-01

VP2156R2

02/18

ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66689-056
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: H3R47K3TBD)	
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:66689-056-99	10 in 1 CASE	11/22/2019	
1		10 in 1 TRAY		
1	NDC:66689-056-01	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 NOT FINAL	part343	11/22/2019	

Labeler - VistaPharm, Inc. (116743084)

Revised: 12/2019 VistaPharm, Inc.