

ACETAMINOPHEN ORAL SOLUTION- acetaminophen oral solution solution

Cardinal Health

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

Active Ingredient

Active ingredient (in each 5 mL cup) □ **Purpose** Acetaminophen USP 160 mg
.....Pain reliever / fever reducer

Purpose

Pain reliever / fever reducer

Acetaminophen 160 mg / 5 mL Unit Dose Cup

Directions

Do not use more than directed Shake well before use

Age (yr)

adults

Dose (mL)

- take 20 mL (640 mg) every 4 to 6 hours
- not to exceed 6 doses in a 24-hour period
- do not use more than 10 days unless directed by a doctor

under 18 years of age

- ask a doctor
-

Keep Out of Reach of Children

Keep out of reach of children.

Warnings and Precautions

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 other inactive ingredients in this product

Warnings

Overdose warning: taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do Not Use

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 other inactive ingredients in this product

Ask Doctor

- has liver disease - is pregnant or breast-feeding

Ask Doctor/Pharmacist

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

Stop Use

Stop use and ask a doctor if:

- **pain gets worse or lasts more than 10 days - new symptoms occur**
- **fever gets worse or lasts more than 3 days - redness or swelling is present**

These could be signs of a serious condition

Inactive Ingredients

Inactive ingredients cherry flavor, citric acid, glycerin, methylcellulose, microcrystalline cellulose, propyl paraben, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Indications and Usage

Uses temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- premenstrual and menstrual cramps
- the common cold
- headache
- toothache
- temporarily reduces fever

Generic Section

Other Information

- store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F)
- protect from excessive moisture - do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free - see bottom of cup for lot number and expiration date

Distributed By:

Cardinal Health

Dublin, OH 43017

L55967620320

Principal Display Panel

Acetaminophen Oral Solution, USP

160 mg/ 5 mL

5 Cups



NDC 55154-8088-5

P115

ACETAMINOPHEN ORAL SOLUTION, USP
160 mg / 5 mL

5 CUPS

Delivers 5 mL

Active ingredient (in each 5 mL cup)	Purpose
Acetaminophen USP 160mg	Pain reliever / fever reducer

Sugar Free Dye Free Alcohol Free

See product insert for prescribing information, precautions and warnings.

STORAGE: Store at 20°- 25° C (68° - 77° F).
Avoid excessive heat 40° C (104° F)

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only.
Keep this and all drugs out of the reach of children.

Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Distributed by Cardinal Health
Dublin, OH 43017
L55967620320

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

ACETAMINOPHEN ORAL SOLUTION

acetaminophen oral solution solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-8088(NDC:0904-6738)
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		
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
SORBITOL (UNII: 506T60A25R)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
METHYLCELLULOSE (15 MPA.S) (UNII: NPU9M2E6L8)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
Product Characteristics				
Color	white (White to light pink)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-8088-5	5 in 1 BAG	04/08/2019	
1		5 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	04/08/2019		

Labeler - Cardinal Health (603638201)