

ACETAMINOPHEN- acetaminophen solution
American Health Packaging

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
Alcohol Free

Purpose

Pain reliever/fever reducer

Active ingredient
(in each 10.15 mL cup)

Acetaminophen 325 mg

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular 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:

- adult takes more than 10 unit dose cups in 24 hours, which is the maximum daily amount
- child takes more than 5 unit dose cups in 24 hours, which is the maximum daily amount
- 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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients of this product

Ask a doctor before use if you have

- liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. 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 children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**

age	dose
adults and children 12 years of age and over	20.3 mL (650 mg) every 4 to 6 hours not to exceed 6 doses in a 24-hour period
children 6 to under 12 years of age	10.15 mL (325 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children under 6 years of age	consult a doctor

Other information

- **Each 10.15 mL contains:** sodium 4 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- protect from light
- a red, cherry flavored solution supplied in the following oral dosage forms:
10.15 mL unit dose cups: 100 cups (10 x 10) NDC 60687-751-56

Inactive ingredients:

Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol and sucrose.

Questions or comments?

Call 1-800-845-8210. You may also report serious side effects to this phone number.

DO NOT USE IF SEAL IS BROKEN.

Distributed by:

American Health Packaging

Columbus, OH 43217

R03/23

Principal Display Panel - Tray Label

Case NDC 60687-751-56/Cup NDC 60687-751-42

ACETAMINOPHEN
ORAL SOLUTION USP

325 mg/10.15 mL

ALCOHOL FREE

Each 10.15 mL contains:

Acetaminophen 325 mg

USUAL DOSAGE: See attached Drug Facts

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

For Institutional Use Only.

T0657C110323 R03/23

Case NDC 60687-751-56/Cup NDC 60687-751-42

**ACETAMINOPHEN
ORAL SOLUTION USP**

325 mg/10.15 mL

ALCOHOL FREE

Each 10.15 mL contains:

Acetaminophen 325 mg

USUAL DOSAGE: See attached Drug Facts

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

For Institutional Use Only.

T0657C110323

R03/23

Principal Display Panel - Cup - 325 mg / 10.15 mL



NDC 60687- **751**-42

**ACETAMINOPHEN
ORAL SOLUTION USP**

Pain Reliever/Fever Reducer

325 mg/10.15 mL

ALCOHOL FREE

Delivers 10.15 mL

Protect from light.

See packaging Drug Facts insert for full
prescribing information and storage.

For Institutional Use Only.

American Health Packaging
Columbus, OH 43217

F0657C110323

ACETAMINOPHEN

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-751
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10.15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

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:60687-751-56	10 in 1 CASE	07/21/2023	
1	NDC:60687-751-48	10 in 1 TRAY		
1	NDC:60687-	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a		

751-42	Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/21/2023	

Labeler - American Health Packaging (929561009)

Revised: 7/2023

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