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 20.3 mL cup)

Acetaminophen 650 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:

- adult takes more than 5 unit dose cups in 24 hours, which is the maximum daily amount
- 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.
- 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 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 under 12 years of age	consult a doctor

Other information

- **Each 20.3 mL contains:** sodium 8 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:
  20.3 mL unit dose cups: 100 cups (10 x 10) NDC 60687-740-37

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?

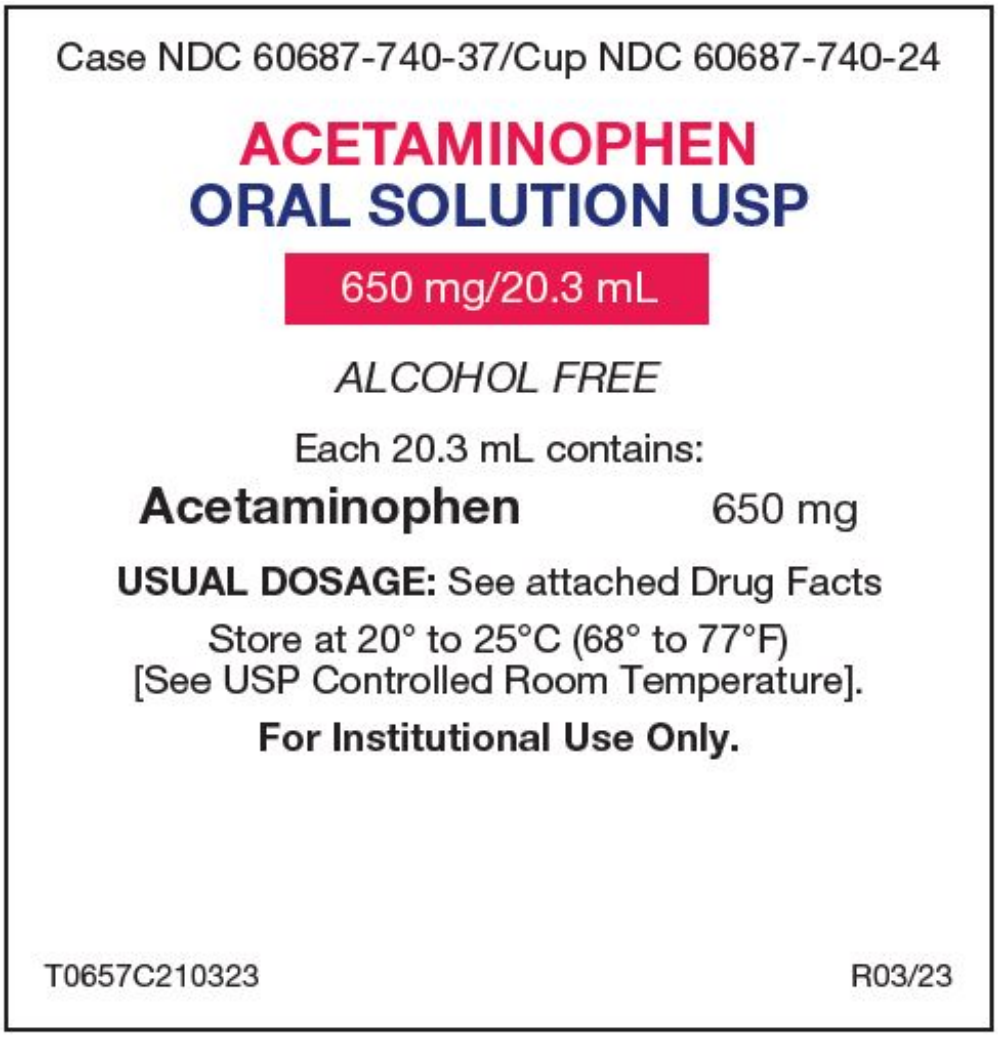
Call 1-800-845-8210. You may also report serious side effects to this phone number.

DO NOT USE IF SEAL IS BROKEN.

Distributed by:
American Health Packaging
Columbus, OH 43217

R03/23

Package/Label Principal Display Panel – Tray Label



Case NDC 60687-740-37/Cup NDC 60687-740-24

ACETAMINOPHEN
ORAL SOLUTION USP

650 mg/20.3 mL

ALCOHOL FREE

Each 20.3 mL contains:

Acetaminophen 650 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.

T0657C210323 R03/23

Package/Label Principal Display Panel – Cup Label – 650 mg/20.3 mL

NDC 60687- **740**-24

ACETAMINOPHEN
ORAL SOLUTION USP
Pain Reliever/Fever Reducer
650 mg / 20.3 mL

ALCOHOL FREE
Delivers 20.3 mL

Protect from light.

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

For Institutional Use Only.

American Health Packaging

Columbus, OH 43217

F0657C210323

ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60687-740
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20.3 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: 3WQ0SDW1A)	
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:60687-740-37	10 in 1 CASE	07/21/2023	
1	NDC:60687-740-53	10 in 1 TRAY		
1	NDC:60687-740-24	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	07/21/2023	

Labeler - American Health Packaging (929561009)

Revised: 7/2023 American Health Packaging