

ACETAMINOPHEN- acetaminophen solution
Cardinal Health 107, LLC

Acetaminophen Oral Solution USP

Alcohol Free

Active ingredient
(in each 5 mL teaspoonful)

ACETAMINOPHEN 160 mg

Purpose

Pain reliever/fever reducer

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 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- 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 before use if the user has 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.

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.

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 4 to under 6 years of age	7.5 mL (240 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children 2 to under 4 years of age	5 mL (160 mg) every 4 hours

children under 2 years of age

not to exceed 5 doses in a 24-hour period
consult a doctor

Other information

- Each 5 mL contains: sodium 2 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- keep tightly closed ■ protect from light
- a red, cherry flavored solution supplied in the following oral dosage forms:
Overbagged with 5 x 20.3 mL unit dose cups per bag, NDC 55154-9449-5

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.

MANUFACTURED BY:

Pharmaceutical Associates, Inc.

Greenville, SC 29605

www.paipharma.com

Distributed By:

Cardinal Health

Dublin, OH 43017

L53336120225

R10/20

Principal Display Panel

NDC 55154-9449-5

ACETAMINOPHEN ORAL SOLUTION USP

650 mg / 20.3 mL

5 CUPS



P107

NDC 55154-9449-5

ACETAMINOPHEN ORAL SOLUTION USP

650 mg / 20.3 mL

5 CUPS

Delivers 20.3 mL

ALCOHOL FREE

Each 20.3 mL contains:

Acetaminophen 650 mg

See product insert for prescribing information, precautions and warnings.

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

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.

PAI Pharma
Greenville, SC 29605
1-800-845-8210
www.paipharma.com
DURA-DOSE®

Distributed by Cardinal Health
Dublin, OH 43017

L53336120225

Lot: Exp:

ACETAMINOPHEN

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-9449(NDC:0121-1971)
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: 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:55154-9449-5	5 in 1 BAG	08/01/2007	
1		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 Drug	M013	08/01/2007	

Labeler - Cardinal Health 107, LLC (118546603)