

ACETAMINOPHEN- acetaminophen tablet
CVS PHARMACY, INC

EXTRA STRENGTH

Acetaminophen Caplets, 500 mg

Pain reliever / Fever reducer

For adults

Contains no aspirin

Active ingredient (in each caplet)

Acetaminophen USP, 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen 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)**

adults and children 12 years and over

- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

children under 12 years

- ask a doctor

Other information

- store between 20-25°C (68-77°F). See USP Controlled Room Temperature.
- see bottom of the label for lot number and expiration date

Inactive ingredients

hydroxypropyl methyl cellulose, polyethylene glycol, povidone k-30, pregelatinized

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-177
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (White to Off-white)	Score	no score
Shape	CAPSULE (Caplet Shape)	Size	17mm
Flavor		Imprint Code	G551
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-177-15	150 in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/26/2024	

Labeler - CVS PHARMACY, INC (062312574)

Registrant - GRANULES USA, INC. (137098864)