ACETAMINOPHEN- acetaminophen tablet SAM'S WEST INC

Extra Strength

Acetaminophen USP, 500mg Caplets

Pain Reliever/Fever Reducer

For Adults

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

Warnings

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

Ask a doctor before use if you have

liver disease

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 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

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 ■ take 2 caplets every 6 hours while symptoms last

■ do not take more than 6 caplets in 24 hours, unless directed by a doctor

 \blacksquare do not use for more than 10 days unless directed by a doctor 12 years and over

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 starch, sodium starch glycolate, stearic acid

Questions or comments?

We would love to hear about your Member's Mark experience! Call us toll-free at **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP



simulate a printed label,

Inside (adhesive side)

ACETAMINOPHEN

acetaminophen tablet

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68196-177

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 500 mg

Inactive II	ngredients
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l	Ingredient Name	Strength

POVIDONE (UNII: FZ989GH94E)

STEARIC ACID (UNII: 4ELV7Z 65AP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
STARCH, CORN (UNII: 08232NY3SJ)		

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	G;551
Contains			

l	P	Packaging			
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:68196-177- 61	600 in 1 BOTTLE; Type 0: Not a Combination Product	02/13/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	02/13/2024		

Labeler - SAM'S WEST INC (051957769)

Revised: 2/2024 SAM'S WEST INC