ACETAMINOPHEN- acetaminophen tablet SAM'S WEST INC

Member's Mark

Acetaminophen Extended-Released Tablets 650mg

Active ingredient (in each caplet)

Acetaminophen USP, 650 mg

Purpose

Pain reliever/fever reducer

Uses

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

Liver warning

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

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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

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

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve

- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor under 18 years of age
- ask a doctor

Other information

- store between 20-25°C (68-77°F)
- do not use if foil inner seal is broken or missing

Inactive Ingredients

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

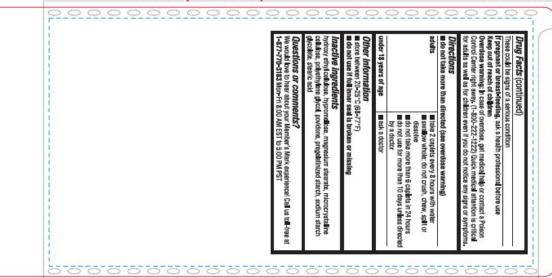
We would love to hear about your Member's Mark experience! Call us toll-free at **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Principal Display Panel



simulate a printed label, fold along dotted line.

Inside (adhesive side)



ACETAMINOPHEN

acetaminophen tablet

Product Information				
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68196-935

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 650 mg

Ingredient Name Strength

MAGNESIUM STEARATE (UNII: 70097M6I30)

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
STEARIC ACID (UNII: 4ELV7Z65AP)
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
STARCH, CORN (UNII: O8232NY3SJ)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POVIDONE K30 (UNII: U725QWY32X)
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)

Product Characteristics					
Color	white (White to off white colored)	Score	no score		
Shape	OVAL (Capsule shaped, biconvex intact film coated tablets)	Size	19mm		
Flavor		Imprint Code	G;650		
Contains					

ı	Packaging						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 NDC:68196-935-	200 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2022				

Marketing I	Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA211544	12/28/2022				

Labeler - SAM'S WEST INC (051957769)

Revised: 2/2024 SAM'S WEST INC