

**ACETAMINOPHEN- acetaminophen tablet**  
**SAM'S WEST INC**

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**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**



COMPARE TO TYLENOL® 8HR  
ARTHRITIS PAIN ACTIVE INGREDIENT\*

TO OPEN: PUSH AND TURN  
CAP READ THE LABEL →  
NDC 68196-935-20

# Arthritis Pain

## ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 MG

**Pain Reliever/Fever Reducer** 8 HR



**200 CAPLETS\*\***  
650 MG EACH  
\*\*CAPSULE-SHAPED  
BI-LAYER TABLETS  
ACTUAL SIZE

• FOR THE TEMPORARY RELIEF  
OF MINOR ARTHRITIS PAIN

**DO NOT USE WITH OTHER MEDICINES  
CONTAINING ACETAMINOPHEN**

**Important: Read all product information before using**  
**Do not use if foil liner seal is broken or missing**

**Drug Facts**  
**Active Ingredient (in each caplet)** Acetaminophen USP, 650 mg Pain reliever/fever reducer

**Uses**

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

**Warnings**  
**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 redness
- hives
- 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

(CONTINUED ON BACK OF LABEL)

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\*This product is not manufactured or distributed by Niche Consumer Healthcare, distributor of Tylenol® 8 HR Arthritis Pain.

Contains No Aspirin

Product of India





how2recycle.info  
PLASTIC WRAP PLASTIC BOTTLE LOT EXP

simulate a printed label,  
fold along dotted line.

Inside (adhesive side)

**Drug Facts (continued)**

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
  - 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 liner seal is broken or missing

**Inactive Ingredients:** hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxanone, 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 1-877-70-3183 Mon-Fri 8:00 AM EST to 5:00 PM EST

## ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-935
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

### Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6130)	

<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z 65AP)	
<b>HYDROXYETHYL CELLULOSE (140 CPS AT 5%)</b> (UNII: 8136Y38GY5)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-935-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2022	

### 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