

ARTHRITIS PAIN- acetaminophen tablet, extended release
SAM'S WEST INC

Sams Club Acetaminophen Extended Release Tablets USP 650 mg

Drug Facts

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Active ingredient (in each caplet)

Acetaminophen 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

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 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	<ul style="list-style-type: none">• 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
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under 18 years of age ask a doctor

Inactive ingredients

carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

- store between 20-25°C (68-77°F)
- The FDA approved dissolution methods differ from USP

Call **1-877-290-4008**

9:00 AM-5:00 PM ET, Monday-Friday

Drug Facts (continued)	
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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ ask a doctor
Other information	
<ul style="list-style-type: none"> ■ store between 20-25°C (68°-77°F) ■ The FDA approved dissolution methods differ from USP 	
Inactive ingredients	
camphor wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polydioxane, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin	
Questions or comments? Call 1-877-290-4008 8:00 AM-5:00 PM ET, Monday-Friday	
Contains No Aspirin	
STOP PEELING	

Adhesive Area

Inside

1/16" Margin

COMPARE TO TYLENOL® 8HR ARTHRITIS PAIN ACTIVE INGREDIENT*

TO OPEN: PUSH AND TURN CAP READ THE LABEL →
NDC 68196-034-02

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

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.

how2recycle.info

PLASTIC PLASTIC WRAP BOTTLE

Varnish Omit Area

LOT: **EXP. DATE:**

USE BY DATE

Drug Facts

Active ingredient (in each caplet)
Acetaminophen 650 mg. [www.merck.com/painrelief](#) 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

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.
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 non-prescription). 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

Drug Facts (continued under label)

*This product is not manufactured or distributed by Kenne Inc., owner of the registered trademark Tylenol® See Arthritis Pain

DISTRIBUTED BY:
SAMS WEST, INC.
BEAUMONTVILLE, AR 72716
Made in India 69R 0625

acetaminophen tablet, extended release

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68196-034

Route of Administration

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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	white (White to off white)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-034-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	08/20/2025	

Labeler - SAM'S WEST INC (051957769)**Registrant** - TIME CAP LABORATORIES,INC (037052099)**Establishment**

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(68196-034)

