

ACETAMINOPHEN- acetaminophen tablet, coated
WAL-MART STORES INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

341R Walmart Acetaminophen 500 mg Tablets

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
- the common cold
- 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 8 caplets in 4 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.

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

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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.**

adults and children 12 years and over:

take 2 caplets (1,000 mg) every 6 hours while symptoms last

do not take more than 6 caplets (3,000 mg) in 24 hours, unless directed by a doctor

do not use more than 10 days unless directed by a doctor

children under 12 years:ask a doctor

Other information

- SODIUM FREE
- store at 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- use by expiration date on package

Inactive ingredients

hypromellose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, titanium dioxide

*may contain this ingredient

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
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

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



EXTRA STRENGTH

Pain Reliever
Acetaminophen
500 mg

**Pain Reliever/
Fever Reducer**
For Adults

Actual Size

500 mg EACH **500 CAPLETS****

**Capsule-Shaped Tablet

Drug Facts

Active ingredient (in each caplet) Purpose
Pain reliever/
Acetaminophen 500 mg, fever reducer

Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ the common cold
■ 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 8 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.

Drug Facts (continued)

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
■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor

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 using and ask a doctor if ■ symptoms do not improve ■ new symptoms occur
■ pain or fever persists or gets worse

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions
■ **do not take more than directed**
adults and children ■ take 2 caplets (1,000 mg) every 6 hours while symptoms last
12 years and over ■ **do not take more than 6 caplets (3,000 mg) 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
■ **SODIUM FREE**
■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
■ use by expiration date on package

Inactive ingredients hypromellose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, titanium dioxide
*may contain this ingredient

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McNEIL-PPC, Inc., Bentonville, AR 72716
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LOT #: 8113136704
EXP. DATE:

Varnish Omit Area

ACETAMINOPHEN			
acetaminophen tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-869
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		
HYPROMELLOSES (UNII: 3NXW29V3WO)			
POVIDONE (UNII: FZ989GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			
MINERAL OIL (UNII: T5L8T28FGP)			
Product Characteristics			
Color	white	Score	no score
Shape	OVAL (caplet)	Size	17mm
Flavor		Imprint Code	TCL341
Contains			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-869-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/01/2020	

Labeler - WAL-MART STORES INC (051957769)

Registrant - TIME CAP LABORATORIES INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(49035-869)

Revised: 2/2023

WAL-MART STORES INC