ACETAMINOPHEN- acetaminophen tablet, coated Kroger Company

Kroger 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:

- 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.

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 in adults
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a seroius 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 (1-800-222-1222) right away. 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 12 years and over:

- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets 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

Other information

- SODIUM FREE
- store between 20-25°C (68-77°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

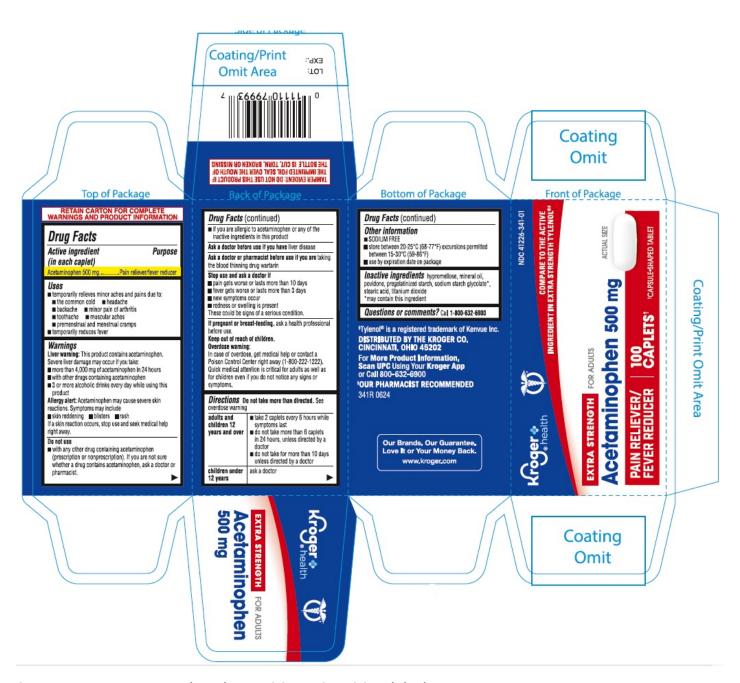
*may contain this ingredient

Questions or comments? Call 1-800-632-6900

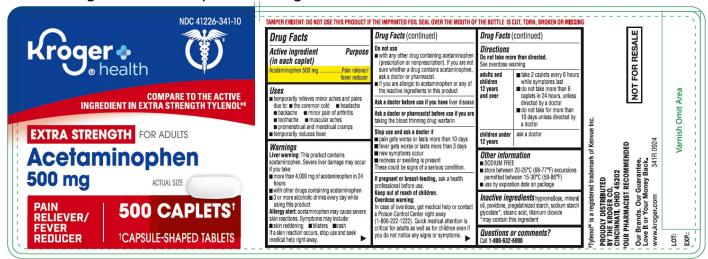
341R- Kroger Acetaminophen 500mg 150ct label

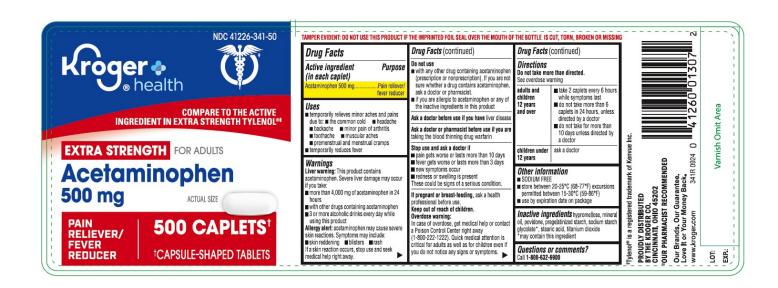


341R- Kroger Acetaminophen 500mg 100 carton



341R- Kroger Acetaminophen 500mg 2x500ct label





ACETAMINOPHEN

acetaminophen tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41226-341

Route of Administration ORAL

Active Ingredient/Active Moiety

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Ingredient Name Basis of Strength Strength

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

Ingredient Name Strength MINERAL OIL (UNII: T5L8T28FGP) SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) HYPROMELLOSES (UNII: 3NXW29V3WO) POVIDONE (UNII: FZ989GH94E) STARCH, CORN (UNII: 08232NY3SJ) STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics						
Color	white	Score	no score			
Shape	OVAL (caplet)	Size	17mm			
Flavor		Imprint Code	TCL341			
Contains						

	Packaging									
1						 	_		 _	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-341- 01	1 in 1 CARTON	06/15/2021	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41226-341- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2021	
3	NDC:41226-341- 10	1 in 1 PACKAGE	05/20/2021	
3		500 in 1 BOTTLE		
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41226-341- 15	150 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2024	

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC Monograph Drug	M013	05/20/2021					

Labeler - Kroger Company (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment							
Name	Address	ID/FEI	Business Operations				
TIME CAP LABORATORIES, INC.		037052099	manufacture(41226-341)				

Establishment							
Name	Address	ID/FEI	Business Operations				
MARKSANS PHARMA LIMITED		677604129	manufacture(41226-341)				

Revised: 6/2025 Kroger Company