

ACETAMINOPHEN- acetaminophen tablet, film coated
TARGET CORPORATION

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.

342R TARGET - APAP 500 MG TABLETS - 11673-342

ACTIVE INGREDIENTS

Active Ingredient: Each tablet contains Acetaminophen 500 mg

INACTIVE INGREDIENTS

CARNAUBA WAX, FD-C RED NO. 40 ALUMINUM LAKE, HYPROMELLOSE, POLYETHYLENE GLYCOL(PEG) 400, POLYETHYLENE GLYCOL (peg) 8000, POVIDONE, PREGELATINIZED STARCH, SODIUM STARCH GLYCOLATE**, STEARIC ACID, SUCRALOSE, TITANIUM DIOXIDE

** MAY CONTAIN THIS INGREDIENT

PURPOSE: Pain Reliever - fever reducer

Keep Out of the Reach of Children: In case of overdose, get medical help or contact a Poison Control Center right away

INDICATIONS AND USAGE:

Pain Reliever – temporarily relieves minor aches and pains due to: the common cold, headache, backache, muscular aches, toothache, premenstrual and menstrual cramps, minor pain of arthritis. Temporarily reduces fever.

Warnings;

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 8 tablets in 24 hours, which is the maximum daily amount; 3 or more alcoholic drinks every day while using this product; with other drugs containing acetaminophen.

Overdose warning: Taking more than the recommended dose (Overdose) may cause liver damage. in case of overdose, get medical help or contact a Poison Control Center (1-800-222-1221) right way. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Do not take more than directed (see overdosage warning)

Adults and children 12 years and over: take 2 tablets (1,000 mg) every 6 hours while symptoms last; do not take more than 6 tablets (3,000 mg) in 24 hours, unless directed by a doctor; do not take for more than 10 days unless directed by a doctor

Children under 12 years: Do not use this adult extra strength product in children under 12 years of age, this will provide more than the recommended dose (overdosage) of acetaminophen and may cause liver damage

24 TABLETS
easy-to-swallow

IF TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS NOT TIGHT PROPERLY OR MISSING.

- **fever** — temporarily relieves minor aches and pains due to headache, the common cold, influenza, minor pain of arthritis, toothache, muscular aches, premenstrual and menstrual cramps
- **sleeping** — temporarily reduces fever

Other warnings: This product contains sodium salicylate. Severe liver damage may occur if you take more than 8 tablets in 24 hours, which is the maximum daily amount.

which is the maximum daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product.

Warning: Astemizole may cause severe allergic reactions. Symptoms may include: swelling of the face, lips, tongue, or throat; difficulty breathing; hives; skin rash; itching; dizziness; headache; nausea; vomiting; diarrhea; and changes in vision. If any of these symptoms occur, stop use and seek medical help right away. Do not use with any other drug containing astemizole. (See also important information about asthma treatment on page 10.)

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 its inactive ingredients in this product, do not use more than 10 days for pain unless directed by a

Strong Factors (continued under label)

94 01 6040 R00 C-000974-01-073
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 Questions? Call 1-800-910-8874

FEEL HERE
OR MORE
DRUG
FACTS

extra strength
acetaminophen
tablets, 500 mg
pain reliever/fever reducer



225 TABLETS
easy-to-swallow

NDC 11673-342-26

WARNING: READ AND FOLLOW THE PRECAUTIONS ON THE INFORMATION PANEL. SEAL OVER THE MOUTH OF THE BOTTLE TO PREVENT TAMPERING OR MISUSE.

THIS IS THE COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each tablet)
Acetaminophen 500 mg

Purpose
Pain reliever/fever reducer

Uses
It temporarily relieves minor aches and pains due to:
■ the common cold ■ headache ■ minor pain of arthritis
■ muscle aches ■ menstrual and menstrual cramps
■ temporarily reduces fever

Warnings
Do not use if you have liver disease. The product contains acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, which is the maximum daily amount.

■ Do not use if you are taking other products 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 over-the-counter). 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.

■ Do not use for more than 10 days for pain unless directed by a doctor
■ Do not use 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 any other drug containing acetaminophen
■ taking any drug that may affect the blood thinning drug warfarin

If you experience any of the following symptoms, stop use and seek medical help right away:
■ loss of appetite ■ nausea ■ vomiting ■ loss of weight ■ loss of energy
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.

Directions
For adults and children 12 years and over: ■ Take 2 tablets (1,000 mg) every 6 hours while symptoms last. ■ Do not take more than 6 tablets (3,000 mg) in 24 hours, unless directed by a doctor. ■ Do not use for more than 10 days unless directed by a doctor.
For children under 12 years: ■ Ask a doctor.

Other information
■ **STORAGE:** Store at 20°C (77°F) excursions permitted between 15°-30°C (59°-86°F). ■ Use by expiration date on package (6/24/01-03/4/02). R001 C-000974-01-073

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342R 0119
Lot No.:
Exp. Date:

ACETAMINOPHEN

acetaminophen tablet, film coated				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-342	
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	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
POVIDONE (UNII: FZ989GH94E)				
Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	TCL342	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-342-42	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2019	
2	NDC:11673-342-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2019	
3	NDC:11673-342-26	225 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	06/01/2019		

Labeler - TARGET CORPORATION (006961700)

Registrant - TIME CAP LABORATORIES INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(11673-342)

Revised: 4/2019

TARGET CORPORATION