

TENSION HEADACHE RELIEF- acetaminophen-caffeine tablet, 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.

11673-839 TARGET - TENSION HEADACHE

ACTIVE INGREDIENTS (IN EACH CAPLET)

Acetaminophen 500 mg - Caffeine 65 mg

colloidal silicon dioxide, pregelatinized starch, D&C red no. 27 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol (PEG 400), povidone stearic acid, talc, titanium dioxide

Pain reliever - Pain reliever aid

USES

• temporarily relieves minor aches and pain due to: • headache - • muscular aches

DIRECTIONS

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- do not use more than directed
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- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 6 caplets in 24 hours
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- children under 12 years: ask a doctor

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1221). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

WARNINGS

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

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- skin reddening
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- blisters
-
- rash

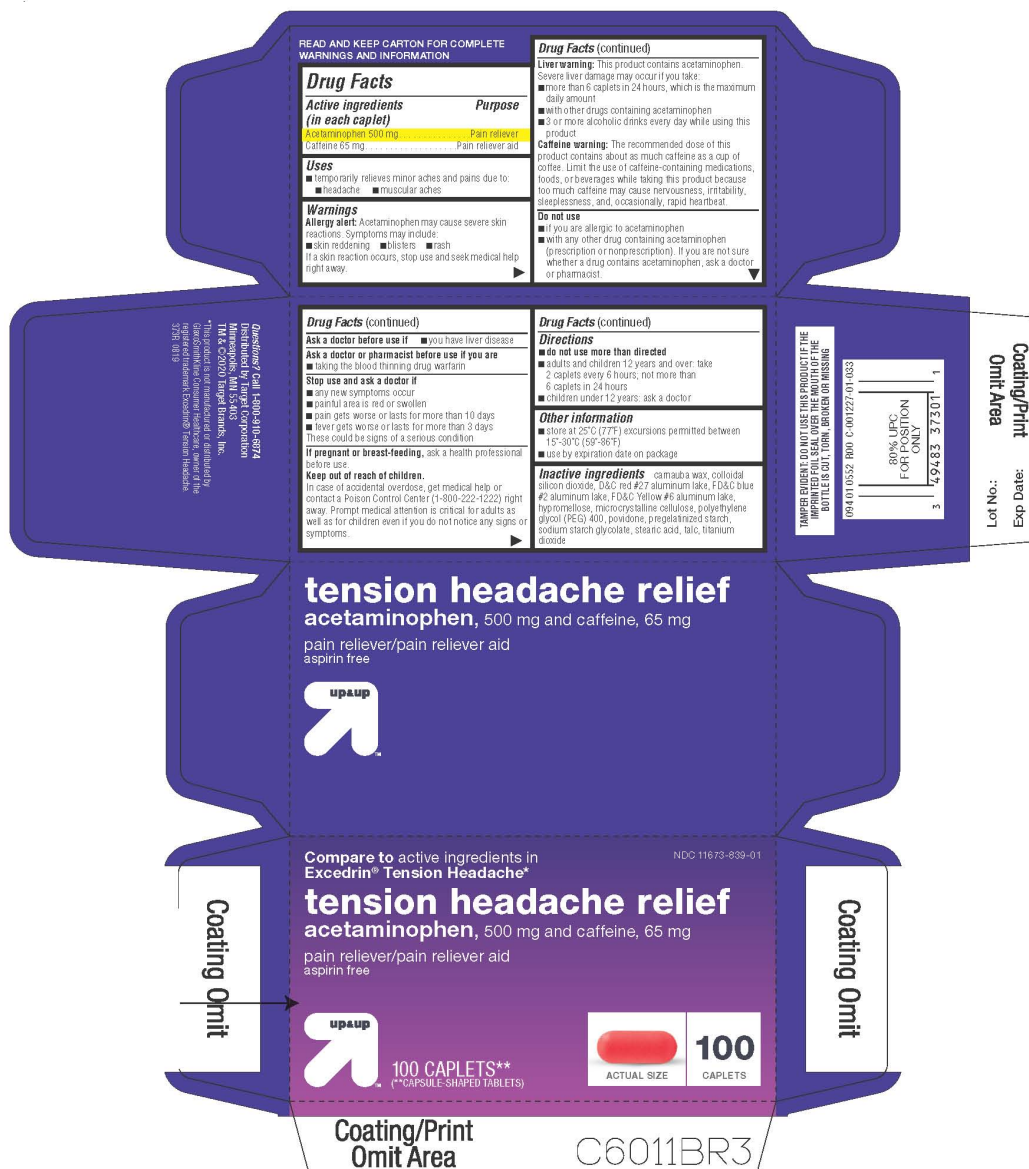
If a skin reaction occurs, stop use and seek medical help right away.

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
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- 3 or more alcoholic drinks every day while using this product

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid

heartbeat.



TENSION HEADACHE RELIEF

acetaminophen-caffeine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-839
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		65 mg

Inactive Ingredients	
Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TALC (UNII: 7SEV7J4R1U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	red	Score	no score
Shape	OVAL ((Caplet))	Size	17mm
Flavor		Imprint Code	TCL373
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:11673-839-01	100 in 1 CARTON; Type 0: Not a Combination Product	02/04/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part343		02/04/2020	

Labeler - TARGET CORPORATION (006961700)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(11673-839)

Revised: 9/2019

TARGET CORPORATION