# HEADACHE RELIEF- acetaminophen-aspirin-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.

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#### **370R 11673-070 HEADACHE RELIEF**

**ACETAMINOPHEN 250 MG** 

ASPIRIN 250 MG (NSAID\*)

**CAFFEINE 65 MG** 

\* NONSTEROIDAL ANTI-INFLAMMATORY DRUG

Carnauba Wax, Colloidal Silicon Dioxide, Hypromellose, Microcrystalline Cellulose, Mineral Oil, Povidone, Pregelatinized Starch, Sodium Starch Gylolate, Stearic Acid, Titanium Dioxide

**PURPOSE** 

PAIN RELIEVER - PAIN RELIEVER AID

**USES** 

TEMPORARILY RELIEVES MINOR ACHES AND PAINS DUE TO: headache - a cold - arthritis - muscular aches - toothache - premenstrual and menstrual cramps

**DIRECTIONS** 

DO NOT USE MORE THAN DIRECTED - DRINK A FULL GLASS OF WATER WITH EACH DOSE - ADULTS AND CHILDREN 12 YEARS AND OVER: TAKE 2 CAPLETS EVERY 6 HOURS, NOT MORE THAN 8 CAPLETS IN 24 HOURS.

CHILDREN UNDER 12 YEARS: ASK A DOCTOR

KEEP OUT OF REACH OF CHILDREN

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

#### REYE'S SYNDROME:

Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

#### ALLERGY ALERT

Aspirin may cause a severe allergic reaction which may include:

hives

facial swelling

asthma (sneezing)

shock

#### 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

### STOMACH BLEEDING WARNING:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

are age 60 or older;

have had stomach ulcers or bleeding problems

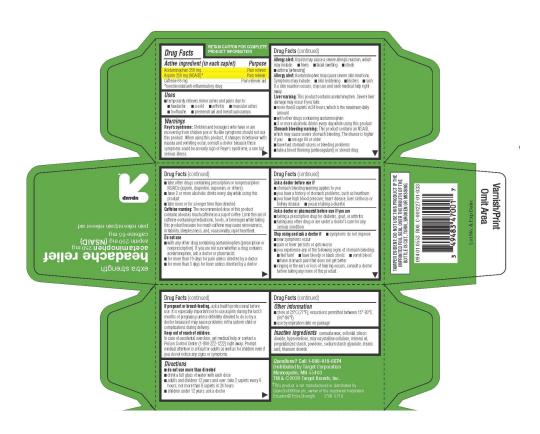
take a blood-thinning (anticoagulant) or steroid drug

take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

take more or for a longer time than directed

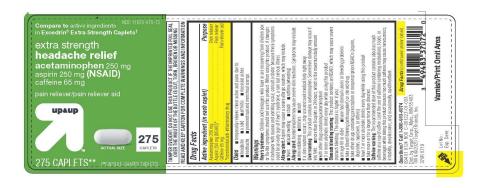
#### **CAFFEINE WARNING:**

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 which while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasionally, rapid heartbeat.



Adhesive Area





# **HEADACHE RELIEF**

acetaminophen-aspirin-caffeine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-070
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
MINERAL OIL (UNII: T5L8T28FGP)		
PO VIDO NE (UNII: FZ989GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		

# SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE (caplet)	Size	17mm
Flavor		Imprint Code	TCL;370
Contains			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:11673-070-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	
2	NDC:11673-070-72	275 in 1 BOTTLE; 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	10/04/2019	

# Labeler - TARGET CORPORATION (006961700)

# **Registrant -** TIME CAP LABORATORIES, INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
TIME CAP LABORATORIES, INC.		037052099	manufacture(11673-070)	

Revised: 1/2020 TARGET CORPORATION