EXTRA STRENGTH 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.

370R NDC 11673-305- TARGET EXTRA STRENGTH HEADACHE RELIEF ASA/APAP/CAF 250/250/65MG

ACETAMINOPHEN 250 MG - ASPIRIN 250 MG (nsaid*) CAFFEINE 65 MG - * NONSTEROIDAL ANIT-INFLAMMATORY DRUG

STEARIC ACID
MINERAL OIL
SILICON DIOXIDE
HYPROMELLOSES
MICROCRYSTALLINE CELLULOSE
STARCH, CORN
POVIDONE
CARNAUBA WAX
TITANIUM DIOXIDE
SODIUM STARCH GLYCOLATE

PURPOSE

PAIN RELIEVER - PAIN RELIEVER AID

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

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 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

WARNINGS

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

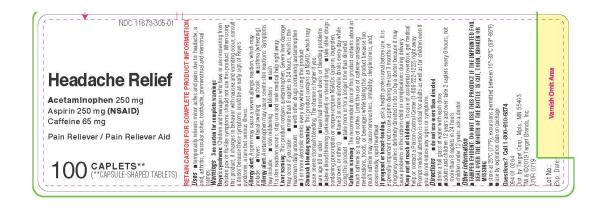
take a blood-thinning (anticoagulant) or steroid drug

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.



acetaminophen-aspirin-caffeine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-305
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAFFEINE (UNII: 3G6 A5W338E) (CAFFEINE - UNII:3G6 A5W338E)	CAFFEINE	65 mg		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	250 mg		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg		

Inactive Ingredients		
Ingredient Name	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
PO VIDO NE (UNII: FZ989 GH94E)		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		
MINERAL OIL (UNII: T5L8T28FGP)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

Product Characteristics			
Color	white	Score	no score
Shape	OVAL (CAPLET)	Size	17mm
Flavor		Imprint Code	TCL370
Contains			

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:11673-305-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 20	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	0 1/0 1/20 20	

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
TIME CAP LABORATORIES, INC.		037052099	manufacture(11673-305)	

Revised: 9/2019 TARGET CORPORATION