

**EXTRA PAIN RELIEF- acetaminophen, aspirin and caffeine tablet, film coated
TIME CAP LABS**

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.

ACTIVE INGREDIENTS

ACETAMINOPHEN 250 MG

ASPIRIN 250 MG (nsaid*)

CAFFEINE 65 MG

* NONSTEROIDAL ANIT-INFLAMMATORY DRUG

INACTIVE INGREDIENTS

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

PAIN RELIEVER - PAIN RELIEVER AID

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 TABLETS EVERY 6 HOURS, NOT MORE THAN 8 TABLETS IN 24 HOURS .

USES

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

Do not use if you have ever had an allergic reaction to acetaminophe, aspirin or any other pain reliever/fever reducer; with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

WARNINGS

REYE'S SYNDROME:

Children and teenages who have or are recovering from chicken pox 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 eary sign of Reye's syndrome, a rare but serious illness.

ALLERY ALERT

Aspirin may cause a severe allergic reaction which may include:

hives

facial swelling

asthma (sheezing)

shock

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;
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 while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasionally, rapid heart beat.

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

If Pregnant or breast-feeding ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Time-Cap Labs, Inc. NDC 49483-370-01
 Compare to the active ingredients in Excedrin®
EXTRA PAIN RELIEF
 Acetaminophen,
 Aspirin (NSAID) and Caffeine
EXTRA STRENGTH
 Pain Reliever
 Pain Reliever Aid
 100 TABLETS

This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin. Form original.
 3705 16444
 Manufactured by:
 Time-Cap Labs, Inc.
 Farmingdale, NY 11735



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

Drug Facts

Active Ingredients (in each tablet)

- Acetaminophen 250 mg
 - Aspirin 250 mg (NSAID)*
 - Caffeine 65 mg
- *nonsteroidal anti-inflammatory drug
- Uses**
- temporarily relieves minor aches and pains due to:
 - headache
 - a cold
 - arthritis
 - muscular aches
 - sinusitis
 - toothache
 - premenstrual and menstrual cramps

Warnings

Read the warnings: Children and teenagers who have or are recovering from chicken pox 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 cause severe stomach bleeding. The chance is higher if you are also taking another medicine that causes stomach ulcers (ulcer) or liver damage. 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 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 taking another medicine that causes stomach ulcers or liver damage
- take a blood thinner (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take 3 or more alcoholic drinks every day while using this product
- 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

LOT NO.:
 EXP. DATE:



acetaminophen, aspirin and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-370
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	capsule (CAPSULE SHAPED TABLET)	Size	18mm
Flavor		Imprint Code	TCL370
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-370-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2016	
2	NDC:49483-370-20	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2013	
3	NDC:49483-370-00	20000 in 1 CARTON; Type 0: Not a Combination Product	02/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/01/2013	

Labeler - TIME CAP LABS (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABS		037052099	manufacture(49483-370)

Revised: 2/2016

TIME CAP LABS