

**TENSION HEADACHE RELIEF- acetaminophen, caffeine tablet**  
**TIME CAP LABS INC**

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**Timely Tension Headache Relief**

***Drug Facts***

***Active ingredients (in each caplet)***

Acetaminophen 500 mg

Caffeine 65 mg

***Purposes***

Pain reliever

Pain reliever aid

***Uses***

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches

***Warnings***

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

- skin reddening
- 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
- 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.

**Do not use**

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

**Ask a doctor before use if**

- you have liver disease

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- any new symptoms occur
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

***Directions***

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

***Other information***

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

***Inactive ingredients*** carnauba wax, colloidal silicon dioxide, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol (PEG) 400, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

***Questions or comments?*** Call **1-877-290-4008**



**Drug Facts (continued)**

**Do not use**

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if** ■ you have liver disease

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- any new symptoms occur
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

These could be signs of a serious condition

**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**

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

**Other Information**

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

**Inactive ingredients:** carnauba wax, colloidal silicon dioxide, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #5 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol (PEG) 400, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or comments call 1-877-290-4008**

**Adhesive Area**

Live Print Area      1/16" Margin      Print Bleed

NDC 49483-373-01

<sup>†</sup>Compare to the Active Ingredient in Excedrin® Tension Headache

**timely**

ASPIRIN FREE  
**Tension Headache Relief**  
Acetaminophen  
500 mg and Caffeine 65 mg  
Pain Reliever / Pain Reliever Aid

**100**  
CAPLETS

**PEEL HERE**

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

Drug Facts	Purpose
<b>Active ingredients (in each caplet)</b> Acetaminophen 500 mg ..... Pain reliever Caffeine 65 mg ..... Pain reliever aid	
<b>Uses</b> ■ temporarily relieves minor aches and pains due to: ■ headache ■ muscular aches	
<b>Warnings</b> <b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If a skin reaction occurs, stop use and seek medical help right away. <b>Liver warning:</b> 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 ■ 3 or more alcoholic drinks every day while using this product <b>Caffeine warning:</b> 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.	

**Drug Facts (continued under label)**

This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, owner of the registered trademark Excedrin® Tension Headache.  
Manufactured by:  
Time-Cap Labs, Inc.  
7 Michae Avenue,  
Farmingdale,  
NY 11735  
373R 0621 3  
4 9 4 8 3 8 3 9 0 1 2

**Varnish Omit Area**

Lot No.:  
Exp. Date:

## TENSION HEADACHE RELIEF

acetaminophen, caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49483-373
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 27 ALUMINUM LAKE</b> (UNII: ZK64F7XSTX)	
<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)	

<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>FD&amp;C BLUE NO. 2 ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule shaped tablet)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL373
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-373-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2023	
2	NDC:49483-373-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/16/2021	

**Labeler** - TIME CAP LABS INC (037052099)

**Registrant** - TIME CAP LABS INC (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABS INC		037052099	manufacture(49483-373)