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

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.

373R Timely 49483-373 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**

Adhesive Area

Drug Facts (continued)

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

Live Print Area

1/16" Margin

Print Bleed

NDC 49483-373-01

timely™

†Compare to the Active Ingredient in Excedrin® Tension Headache

ASPIRIN FREE

Tension Headache Relief

Acetaminophen
500 mg and Caffeine 65 mg

Pain Reliever / Pain Reliever Aid

100 CAPLETS

TCL 373

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

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid

Uses
- temporarily relieves minor aches and pains due to:
  - headache ■ muscular aches

Warnings

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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 Michael Avenue,
Farmingdale,
NY 11735

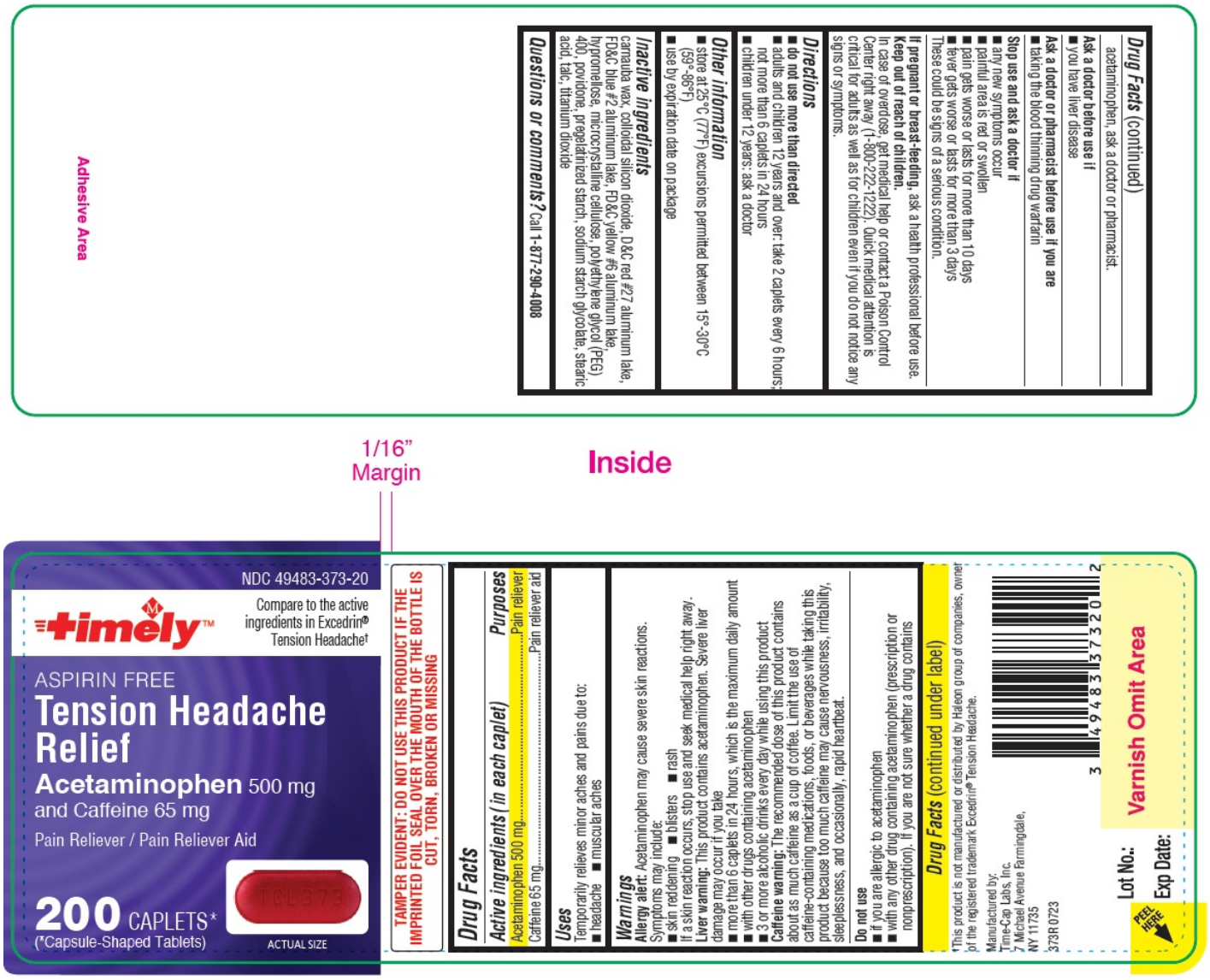
373R 0621 3

4 94483 83901 2

PEEL HERE

Lot No.:
Exp. Date:

Varnish Omit Area



TENSION HEADACHE RELIEF

acetaminophen, caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49483-373
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 27 (UNII: 2LRS185U6K)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
STARCH, CORN (UNII: O8232NY3SJ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

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 not final	part343	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)

Revised: 9/2023 TIME CAP LABS INC