

**ALERT- caffeine tablet, film coated**  
**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.*

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**343R- ALERT**

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**Active ingredient (in each tablet)**

Caffeine 200 mg

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**Purpose**

Alertness aid

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**Uses**

helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

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**Warnings**

**For occasional use only**

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**Do not use**

- in children under 12 years of age
  - as a substitute for sleep
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**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.

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**Stop use and ask a doctor if**

fatigue or drowsiness persists or continues to recur

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**If pregnant or breast-feeding,**

ask a health professional before use.

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**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

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**Directions**

- adults and children 12 years and over: take 1 tablet not more often than every 3 to 4 hours
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**Other information**

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat (greater than 100°F) or humidity
- use by expiration date on package

**Inactive ingredients**

carnauba wax, colloidal silicon dioxide, D-C yellow #10 aluminum lake, dextrans, FD-C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Adhesive Area

**Drug Facts (continued)**

**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.

**Stop use and ask a doctor** if fatigue or drowsiness persists or continues to recur.

**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.

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STOP PEELING

NDC 49483-343-44

**Time-Cap Labs, Inc.**

\*Compare to the active ingredient in Vivarin®

**Alert**

**Caffeine 200 mg**

ALERTNESS AID

*Equal to About a Cup of Coffee*

40 TABLETS



\*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, L.P., owner of the registered trademark Vivarin®. Manufactured by: Time-Cap Labs, Inc. Farmingdale, NY 11735

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

PEEL HERE FOR MORE DRUG FACTS

**Drug Facts**

<b>Active ingredient</b> (in each tablet)	<b>Purpose</b>
Caffeine 200 mg. ....	Alertness aid
<b>Uses</b>	helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness
<b>Warnings</b> For occasional use only	<p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ in children under 12 years of age</li> <li>■ as a substitute for sleep</li> </ul>

LOT NO.: \_\_\_\_\_ EXP. DATE: \_\_\_\_\_

# ALERT

caffeine tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-343
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	200 mg

## Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DEXTRATES (UNII: G263M44RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL;343
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-343-44	40 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part340	11/30/2011	

Labeler - Time Cap Labs, Inc (037052099)

## Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Labs, Inc		037052099	manufacture(49483-343)

Revised: 12/2018

Time Cap Labs, Inc