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.

343R- ALERT

Active ingredient (in each tablet) Caffeine 200 mg

Purpose

Alertness aid

Uses

helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

Warnings

For occasional use only

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Do not use

• in children under 12 years of age

• as a substitute for sleep

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.

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.

Directions

• adults and children 12 years and over: take 1 tablet not more often than every 3 to 4 hours

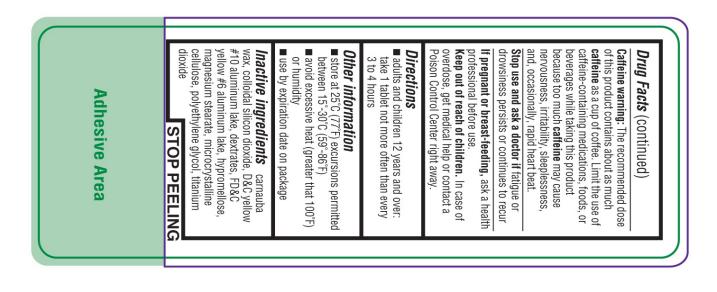
Other information

- 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

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Inactive ingredients

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





ALERT caffeine tablet, film coate	ed			
Product Information				
Product Type		DTC DRUG It	em Code (Source)	NDC:49483-343
Route of Administration	ORAL			
Active Ingredient/Ac	tive Moiety			
0	Ingredient Na	Basis of St	rength Streng	
CAFFEINE (UNII: 3G6A5W3	38E) (CAFFEINE - UN	CAFFEINE	200 mg	
Inactive Ingredients				
	Ingi	redient Name		Strength
CARNAUBA WAX (UNII: R1	Ũ			
SILICON DIOXIDE (UNII: E	TJ7Z6XBU4)			
D&C YELLOW NO. 10 (UN	NII: 35SW5USQ3G)			
DEXTRATES (UNII: G263M	I44RU)			
FD&C YELLOW NO.6 (UN	NII: H77VEI93A8)			
HYPROMELLOSE 2910 (6				
HYPROMELLOSE 2910 (1		W2JZ0W)		
MAGNESIUM STEARATE (
CELLULOSE, MICROCRY				
POLYETHYLENE GLYCO		K8M3B)		
TITANIUM DIO XIDE (UNII:	. 1561A9 V256)			
Product Characterist	tics			
Color	yello w	Score		no score
Shape	ROUND	Size		
Flavor		Imprint Code		TCL;343
Contains				
Packaging				
# Item Code	Packagel	Description	Marketing Start Date	Marketing End D
1 NDC:49483-343-44 40 in	•	-	-	Lind D
Marketing Inforn				
Marketing Category	Application Number	r or Monograph Citat	ion Marketing Start Date	Marketing End D

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

Revised: 12/2018

Time Cap Labs, Inc