# ALERTNESS AID STAY AWAKE- caffeine tablet Healthlife of USA

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.

-----

## **Alertness Aid Stay Awake**

## **Drug Facts**

#### **Purpose**

Alertness Aid

#### **Active Ingredient (in each tablet)**

Caffeine 200mg

#### Uses

• Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

#### Warnings

## For occasional use only

#### 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 c ase 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 than every 3 to 4 hours

#### Other Information

- Store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) or humidity
- Avoid excessive heat (greater than 100°F) or humidity
- Read all product information before using
- ITAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

## **Inactive Ingredients**

- Carnauba wax
- Colloidal silicon dioxide
- D&C yellow #10 aluminium lake
- Dextrates
- FD&C yellow#6 aluminium lake
- Hypeomellose
- Magnesium stearate
- Microcrystalline cellulose
- Polyethylene glycol
- Titanium dioxide

#### Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM -5PM EST or www.healthlifeofusa.com

Alertness Aid Stay Awake Caffeine 200mg / alertness Aid Safe & Effective Helps Restore Alertness

## Compare to Vivarin® active ingredients

Distributed by: Healthlife of USA LLC Rahway NJ 07065 www.healthlifeofusa.com



#### ALERTNESS AID STAY AWAKE

caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-132
Route of Administration	ORAL		

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6 A5W338E) (CAFFEINE - UNII:3G6 A5W338E)	CAFFEINE	200 mg

Inactive Ingredients				
Ingredient Name	Strength			
CARNAUBA WAX (UNII: R12CBM0 EIZ)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
DEXTRATES (UNII: G263MI44RU)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSES (UNII: 3NXW29 V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6130)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics			
Color	ye llo w	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1 NDC:69517-132-16	1 in 1 CARTON	05/31/2017		
1	16 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part340	05/31/2017		

## Labeler - Healthlife of USA (079656178)

Establishment			
Name	Address	ID/FEI	Business Operations
Healthlife of USA		079656178	repack(69517-132)

Establishment			
Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(69517-132), pack(69517-132)

Revised: 6/2017 Healthlife of USA