ALERTNESS AID - caffeine tablets, 200 mg tablet, coated We Care Distributor 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.

ALERTNESS AID - Caffeine Tablets, 200 mg

Drug Facts

Active ingredient (in each tablet) Purpose

Caffeine 200 mg......Alertness aid

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 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.

Directions

■ adults and children 12 years of age or 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

Inactive ingredients

carnauba wax, colloidal silicon dioxide, D&C yellow no 10 aluminum lake, dextrates, FD&C yellow no 6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredients in Vivarin®

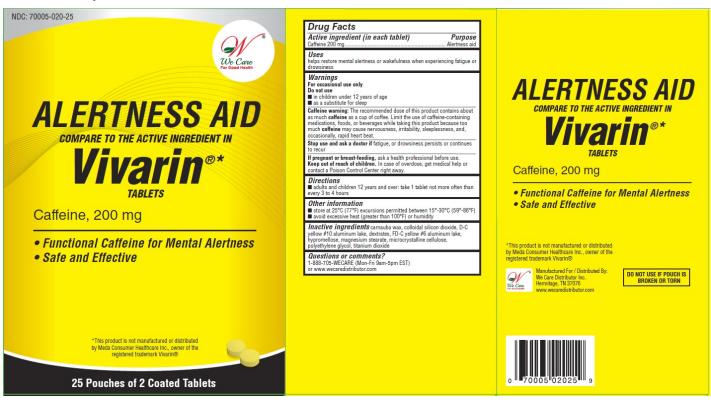
ALERTNESS AID

Caffeine Tablets, 200 mg

TO OPEN

PUSH IN TAB AND PULL OUT

25 Pouches of 2 Tablets Each



ALERTNESS AID

caffeine tablets, 200 mg tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-020
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: 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)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics				
Color	yello w	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:70005-020-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-020-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-020-02	2 in 1 POUCH		
3		2 in 1 POUCH; 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	03/07/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment				
Name	Address	ID/FEI	Business Operations	
Time Cap Labs, Inc		037052099	manufacture(70005-020)	

Revised: 3/2016 We Care Distributor Inc.