

CAFFEINE- caffeine tablet
AAA Pharmaceutical, 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.

Caffeine Tablets

Drug Facts

Active ingredient (in each tablet)

Caffeine 200 mg

Purpose

Alertness aid

Use

helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

Warnings

Do not use in children under 12 years of age

When using this product limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

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

For occasional use only. Not intended as a substitute for sleep.

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 and over: take 1 tablet not more often than every 3 to 4 hours

Other information

- each tablet contains: **calcium 80 mg**
- store at room temperature 15°-30°C (59°-86°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, dibasic calcium phosphate, FD&C yellow #6, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Distributed by:

AAA Pharmaceutical, Inc.

681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 16 Tablet Carton

RESTORE u

NDC 57344-020-01

†COMPARE TO THE ACTIVE
INGREDIENT IN VIVARIN®

Stay Awake

ALERTNESS AID

Caffeine

16 TABLETS - 200 mg each

NC

NC

NC

Drug Facts (continued)

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Active ingredient (in each tablet)
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Purpose
▲ Use helps restore mental alertness or wakes you as when experiencing fatigue or drowsiness



RESTORE^u

NDC 57344-020-01

COMPARE TO THE ACTIVE INGREDIENT IN VIVARIN®

Stay Awake

ALERTNESS AID
Caffeine



16 TABLETS - 200 mg each

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F102001RES_RO

DO NOT USE IF BLISTER UNITS ARE TO RN OR BROKEN

This product is not manufactured or distributed by Meda Consumer Healthcare, Inc., distributor of Vivarin®



CAFFEINE
caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-020	
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	
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
	D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)			
	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics				
Color	YELLOW	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	LL64;57344	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-020-01	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		
2	NDC:57344-020-02	5 in 1 CARTON		
2		8 in 1 BLISTER PACK		
3	NDC:57344-020-03	10 in 1 CARTON		
3		8 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part340	12/15/2012		

Labeler - AAA Pharmaceutical, Inc. (181192162)

Establishment

Name	Address	ID/FEI	Business Operations
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AAA Pharmaceutical, Inc.		18 119 2162	MANUFACTURE(57344-020)
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Establishment

Name	Address	ID/FEI	Business Operations
AAA Pharmaceutical, Inc.		0 10 411533	PACK(57344-020)

Revised: 12/2012

AAA Pharmaceutical, Inc.