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

 $^{\dagger}\text{COMPARE}$ TO THE ACTIVE INGREDIENT IN VIVARIN®

Stay Awake

ALERTNESS AID

Caffeine

16 TABLETS - 200 mg each

NO

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Drug Facts (continued)

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Purpose Mermessaid

Active ingredient (in each tablet)

Drug Facts



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NDC 57344-020-01

†COMPARETO THE ACTIVE



ALERTNESS AID
Caffeine

16 TABLETS - 200 mg each

Distributed by:
AAA Pharmaceutical, Inc
681 Main Street

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

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



CAFFEINE

caffeine tablet

Product Information

mberton, NJ 08048

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:57344-020
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAFFEINE (CAFFEINE)	CAFFEINE	200 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US	
FD&C YELLOW NO. 6	
MAGNESIUM STEARATE	
CELLULOSE, MICRO CRYSTALLINE	
STARCH, CORN	

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

AAA Pharmaceutical, Inc.	18 119 216 2	MANUFACTURE(57344-020)

Establishment				
Name	Address	ID/FEI	Business Operations	
AAA Pharmaceutical, Inc.		010411533	PACK(57344-020)	

Revised: 12/2012 AAA Pharmaceutical, Inc.