

STAY AWAKE- caffeine tablet
Freds 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.

Drug Facts

Active ingredient (in each tablet)

Caffeine 200 mg

Purpose

Alertness aid

Uses

- helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

Warnings

- the recommended dose of this product contains about as much caffeine as one 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.
- for occasional use only. Not intended for use as a substitute for sleep.
- **do not give to children under 12 years of age**

Stop use and ask a doctor if

fatigue or drowsiness persists or continues to recur.

If pregnant or breast-feeding,

ask a health care 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 (200 mg) not more often than every 3 to 4 hours

Other information

- **each tablet contains:** calcium 60 mg
- store at controlled room temperature 15°-30°C (59°-86°F)
- avoid excessive heat and humidity

Inactive ingredients

cellulose*, croscarmellose sodium*, D&C Yellow #10 aluminum lake, dicalcium phosphate, FD&C

Yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, silica, sodium starch glycolate*, starch*

*contains one or more of these ingredients

Questions or comments?

Call toll free **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Stay Awake

Caffeine, 200 mg

Maximum Strength Alertness Aid

Safe & Effective

Compare to the active ingredient in Vivarin®**

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

**This product is not manufactured or distributed by GlaxoSmithKline, owner of the registered trademark Vivarin®.

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION
TAMPER EVIDENT USE ONLY IF BLISTERS ARE INTACT**

Package Label



fred's Stay Awake Tablets

STAY AWAKE

caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-250
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
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	212;212
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-250-16	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part340	03/01/2013	

Labeler - Freds Inc (005866116)**Registrant** - P and L Development of New York Corporation (800014821)

