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 LABEL	Item Code (Source)	NDC:55315-250
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	
D&C YELLOW NO. 10		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US		
FD&C YELLOW NO. 6		
MAGNESIUM STEARATE		
CELLULO SE, MICRO CRYSTALLINE		
SILICON DIO XIDE		
PO WDERED CELLULO SE		
CROSCARMELLOSE SODIUM		
SODIUM STARCH GLYCOLATE TYPE A CORN		
STARCH, CORN		
ALUMINUM O XIDE		

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)

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