

STAY AWAKE- caffeine tablet, coated

Marc Glassman, 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.

Stay Awake

Active ingredient(s)

Caffeine 200mg

Purpose

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

When using this product

limit the use of caffeine- containing medications, foods or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and occasional 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 occur.

Pregnancy/Breastfeeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- **Adults and children 12 years of age and older:** take 1 tablet not more often than every 3 to 4 hours
- **Children under 12 years of age:** do not use

Other information

- store at room temperature 68°-77°F (20°-25°C)
- avoid excessive heat (greater than 100°F)
- **do not use if carton is opened or blister unit is broken**

Inactive ingredients

croscarmellose sodium, D&C yellow #10 aluminum lake, dicalcium phosphate, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

Principal Display Panel

Caffeine 200 mg
Stay Awake
Marc's

NDC 68998-076-84 **Compare to Vivarin®**
Active Ingredient*

Marc's

Stay Awake

Caffeine 200 mg

Maximum Strength Alertness Aid

Equals about 1 cup of coffee  **16 Tablets**

Marc's
Stay Awake
Caffeine 200 mg

Distributed by:
 Marc Glassman, Inc.
 West 130th Street
 Cleveland, OH 44130



LB1243
 R1116

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

<p>Drug Facts</p> <p>Active Ingredient (in each tablet) Caffeine 200mg.....Alertness aid</p> <p>Purpose</p> <p>uses helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness</p> <p>Warnings For occasional use only.</p> <p>Do not use ■ in children under 12 years of age ■ as a substitute for sleep</p> <p>When using this product limit the use of caffeine-containing medications, foods or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and occasional rapid heartbeat. The recommended dose of this product contains about as much caffeine as a cup of coffee.</p> <p>Stop use and ask a doctor if fatigue or drowsiness persists or continues to occur.</p>	
<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.</p> <p>Directions ■ Adults and children 12 years of age and older: take 1 tablet not more often than every 3 to 4 hours ■ Children under 12 years of age: do not use</p> <p>Other information ■ store at room temperature (68°-77°F (20°-25°C) ■ avoid excessive heat (greater than 100°F) ■ do not use if carton is opened or blister unit is broken</p> <p>Inactive ingredients croscarmellose sodium, D&C yellow #10 aluminum lake, dicalcium phosphate, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide</p>	

Stay Awake

STAY AWAKE

caffeine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-076
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	AZ;076
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-076-84	2 in 1 CARTON	07/01/2014	
1		8 in 1 BLISTER PACK; 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	07/01/2014	

Labeler - Marc Glassman, Inc. (094487477)

Revised: 12/2016

Marc Glassman, Inc.