

STAY AWAKE- caffeine tablet

Major Pharmaceuticals

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.

Major 44-226-delisted

Active ingredient (in each tablet)

Caffeine 200 mg

Purpose

Alertness aid

Uses

helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness

Warnings

For occasional use only

Caffeine warning: The recommended dose of this product contains about as much **caffeine** as a 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.

Do not use

- in children under 12 years
- as a substitute for sleep

Stop use and ask a doctor if

fatigue or drowsiness persists or continues to recur.

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

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C yellow #10 aluminum lake, dextrose, dicalcium phosphate, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, silica gel

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR[®]

NDC 0904-7955-44

STAY AWAKE

Maximum Strength • Alertness Aid

- For Fast Pick-Up - Safe As Coffee
- Contains 200 mg Caffeine
Equal to About A Cup Of Coffee

*Compare to the
active ingredient in

Vivarin[®]

16 Tablets

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed
by Meda Consumer Healthcare, owner of the
registered trademark Vivarin[®].

50844 REV0412E22621

Distributed by **MAJOR[®] PHARMACEUTICALS**

31778 Enterprise Drive, Livonia, MI 48150 USA

M-17 Rev. 01/13 Re-order No. 700553

16 Tablets

STAY AWAKE

Safe and Effective - as reported by a government appointed panel of experts.

Use as Directed

MAJOR

NDC 0904-7955-44

STAY AWAKE

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16 Tablets



3 09047 95544 2

No print/No varnish
Lot & Exp date

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Drug Facts (continued)
Questions or comments? (800) 616-2471

B-1212-226-21
REV0412E22621

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Caffeine 200 mg.....Alertness aid</p> <p>Uses helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness</p> <p>Warnings For occasional use only Caffeine warning: The recommended dose of this product contains about as much caffeine as a 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.</p> <p>Do not use ■ in children under 12 years ■ as a substitute for sleep</p>	
<p>Drug Facts (continued) Stop use and ask a doctor if fatigue or drowsiness persists or continues to recur. 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.</p>	
<p>Directions ■ adults and children 12 years and over: take 1 tablet not more often than every 3 to 4 hours</p>	
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RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

LEBGG626C

A495

STAY AWAKE

caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7955
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
ANHYDRO US DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTROSE (UNII: IY9XDZ35W2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	44;226
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7955-44	2 in 1 CARTON	11/21/1996	11/15/2021
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	11/21/1996	11/15/2021

Labeler - Major Pharmaceuticals (191427277)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0904-7955)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0904-7955)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0904-7955)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0904-7955)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0904-7955)

Revised: 3/2019

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