

SOMINEZE- humulus lupulus, passiflora incarnata, valeriana officinalis, ambrosia artemisiaefolia, arsenicum album, coffea tosta, lycopodium clavatum, nux vomica, phosphoricum acidum, silicea liquid
BioActive Nutritional, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS:

ACTIVE INGREDIENTS:

Ambrosia Artemisiaefolia 12X, Arsenicum Album 12X, Coffea Tosta 12X, Humulus Lupulus 3X, Lycopodium Clavatum 12X, Nux Vomica 12X, Passiflora Incarnata 3X, Phosphoricum Acidum 12X, Silicea 12X, Valeriana Officinalis 3X.

PURPOSE:

Ambrosia Artemisiaefolia – difficulty sleeping,** Arsenicum Album - fatigue,** Coffea Tosta - sleeplessness,** Humulus Lupulus – nervous exhaustion,** Lycopodium Clavatum - irritability,** Nux Vomica - irritability,** Passiflora Incarnata – restless sleep,** Phosphoricum Acidum – fatigue,** Silicea - fatigue,** Valeriana Officinalis – tossing & turning**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

USES:

For temporary relief of fatigue, insomnia with restlessness of the legs, irritability, light sleep with drowsiness in the morning.**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

WARNINGS:

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.

Do not use if tamper evident seal is broken or missing.

Store in a cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- 10 drops orally, 3 times a day or as directed by a health care professional.
- Consult a health care professional for use in children under 12 years of age.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:

BioActive Nutritional, Inc.

1803 N. Wickham Rd.

Melbourne, FL 32935

bioactivenutritional.com

1-800-288-9525

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

SOMINEZE

HOMEOPATHIC

1 fl. oz. (30 mL)

BIOActive
Nutritional

SOMINEZE

HOMEOPATHIC

1 fl. oz. (30mL) 25% Ethanol

Do not use if Tamper Evident seal is broken or missing.

Drug Facts

Active Ingredients	Purpose
Ambrosia	
Artemisiaefolia 12X.....	difficulty sleeping**
Arsenicum Album 12X.....	fatigue**
Coffea Tosta 12X.....	sleeplessness**
Humulus	
Lupulus 3X.....	nervous exhaustion**
Lycopodium Clavatum 12X.....	irritability**
Nux Vomica 12X.....	irritability**
Passiflora Incarnata 3X.....	restless sleep**
Phosphoricum Acidum 12X.....	fatigue**
Silicea 12X.....	fatigue**
Valeriana	
Officinalis 3X.....	tossing & turning**

Drug Facts (continued under label)


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Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0379
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	3 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	3 [hp_X] in 1 mL
AMBROSIA ARTEMISIIFOLIA WHOLE (UNII: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA - UNII:9W34L2CQ9A)	AMBROSIA ARTEMISIIFOLIA WHOLE	12 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
COFFEA ARABICA SEED, ROASTED (UNII: 9H58JRT35E) (COFFEA ARABICA SEED, ROASTED - UNII:9H58JRT35E)	COFFEA ARABICA SEED, ROASTED	12 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	12 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	12 [hp_X] in 1 mL
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	PHOSPHORIC ACID	12 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0379-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/14/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/14/2015	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0379) , api manufacture(43857-0379) , label(43857-0379) , pack(43857-0379)