

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:

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

INDICATIONS:

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

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 cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

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. Consult a physician for use in children under 12 years of age.

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

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:

BIOACTIVE NUTRITIONAL

Melbourne, FL 32935

For Nutritional Information write:

BioActive Nutritional, Inc.

1803 N. Wickham Rd.

Melbourne, FL 32935

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

SOMINEZE

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935
bioactivenutritional.com

SOMINEZE

HOMEOPATHIC

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

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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 (UNII: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA - UNII:9W34L2CQ9A)	AMBROSIA ARTEMISIIFOLIA	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)