

HEADACHE TONIC- carduus marianus, pyrethrum parthenium, secale cornutum, aconitum napellus, belladonna, bryonia (alba), gelsemium sempervirens, glonoinum, melilotus officinalis, nux vomica, sepia, spigelia anthelmia 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:

Carduus Marianus MT, Pyrethrum Parthenium 6X, Secale Cornutum 6X, Aconitum Napellus 12X, Belladonna 12X, Bryonia (Alba) 12X, Gelsemium Sempervirens 12X, Glonoinum 12X, Melilotus Officinalis 12X, Nux Vomica 12X, Sepia 12X, Spigelia Anthelmia 12X.

INDICATIONS:

For temporary relief of throbbing headache with muscular soreness of neck & shoulder pain & fullness, especially in the forehead, occiput and temples, & bursting, splitting headache.

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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INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol.

QUESTIONS:

Distributed by:
BioActive Nutritional, Inc.

1803 N. Wickham Rd.
Melbourne, FL 32935
bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional
HEADACHE TONIC
HOMEOPATHIC
2 FL OZ (60 ml)



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LOT:

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HEADACHE TONIC
HOMEOPATHIC

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0507
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MILK THISTLE (UNII: U946SH95EE) (MILK THISTLE - UNII:U946SH95EE)	MILK THISTLE	1 [hp_X] in 1 mL
TANACETUM PARTHENIUM (UNII: 6GE7Z0761K) (TANACETUM PARTHENIUM - UNII:6GE7Z0761K)	TANACETUM PARTHENIUM	6 [hp_X] in 1 mL
CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N)	CLAVICEPS PURPUREA SCLEROTIUM	6 [hp_X] in 1 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	12 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	12 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T71046X72B) (BRYONIA ALBA ROOT - UNII:T71046X72B)	BRYONIA ALBA ROOT	12 [hp_X]

BRIONIA ALBA ROOT (UNII: 1794012B) (BRIONIA ALBA ROOT - UNII:1794012B)	BRIONIA ALBA ROOT	in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	12 [hp_X] in 1 mL
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	12 [hp_X] in 1 mL
MELILOTUS OFFICINALIS TOP (UNII: GM6P02J2DX) (MELILOTUS OFFICINALIS TOP - UNII:GM6P02J2DX)	MELILOTUS OFFICINALIS TOP	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
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	12 [hp_X] in 1 mL
SPIGELIA ANTHELMIA (UNII: WYT05213GE) (SPIGELIA ANTHELMIA - UNII:WYT05213GE)	SPIGELIA ANTHELMIA	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0507-1	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/30/2019	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0507, 43857-0507) , api manufacture(43857-0507) , pack(43857-0507)