

FOOD ADDITIVES- berberis vulgaris, chelidonium majus, trifolium pratense, glycyrrhiza glabra, lappa major, phytolacca decandra, rhamnus frangula, rhamnus purshiana, stillingia sylvatica, xanthoxylum fraxineum, arsenicum album, belladonna, lycopodium clavatum, natrum sulphuricum, phosphoricum acidum 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:

Berberis Vulgaris 3X, Chelidonium Majus 3X, Trifolium Pratense 3X, Glycyrrhiza Glabra 4X, Lappa Major 4X, Phytolacca Decandra 4X, Rhamnus Frangula 4X, Rhamnus Purshiana 4X, Stillingia Sylvatica 4X, Xanthoxylum Fraxineum 4X, Arsenicum Album 12X, Belladonna 12X, Lycopodium Clavatum 12X, Natrum Sulphuricum 12X, Phosphoricum Acidum 12X

INDICATIONS:

For temporary relief of exhaustion, flatulence and mood swings.

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.

DIRECTIONS:

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol.

KEEP OUT OF REACH OF CHILDREN:

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INDICATIONS:

For temporary relief of exhaustion, flatulence and mood swings.

QUESTIONS:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.

Melbourne, FL 32935
bioactivenutritional.com

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

FOOD ADDITIVES

HOMEOPATHIC

1 FL OZ (30 ml)



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.

LOT:

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FOOD ADDITIVES

HOMEOPATHIC

ACTIVE INGREDIENTS:

Berber Vulg 3X, Chelidonium Maj 3X, Trifolium Prat 3X, Glycyrrhiza 4X, Lappa 4X, Phytolacca 4X, Rhamnus Frang 4X, Rhamnus Pursh 4X, Stillingia 4X, Xanthoxylum 4X, Arsenicum Alb 12X, Belladonna 12X, Lycopodium 12X, Nat Sulphuricum 12X, Phosphoricum Ac 12X.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0168
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	3 [hp_X] in 1 mL
CHELIDONIUM MAJUS (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	3 [hp_X] in 1 mL
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828) (TRIFOLIUM PRATENSE FLOWER - UNII:4JS0838828)	TRIFOLIUM PRATENSE FLOWER	3 [hp_X] in 1 mL
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) (GLYCYRRHIZA GLABRA - UNII:2788Z9758H)	GLYCYRRHIZA GLABRA	4 [hp_X] in 1 mL
ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3) (ARCTIUM LAPPA ROOT - UNII:597E9B3Z3)	ARCTIUM LAPPA ROOT	4 [hp_X] in 1 mL

UNII:597E9B13Z3)	ARCTIUM LAPPULA ROOT	in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	4 [hp_X] in 1 mL
FRANGULA ALNUS BARK (UNII: S2D77IH61R) (FRANGULA ALNUS BARK - UNII:S2D77IH61R)	FRANGULA ALNUS BARK	4 [hp_X] in 1 mL
FRANGULA PURSHIANA BARK (UNII: 4VBP01X99F) (FRANGULA PURSHIANA BARK - UNII:4VBP01X99F)	FRANGULA PURSHIANA BARK	4 [hp_X] in 1 mL
STILLINGIA SYLVATICA ROOT (UNII: QBR70R4FBK) (STILLINGIA SYLVATICA ROOT - UNII:QBR70R4FBK)	STILLINGIA SYLVATICA ROOT	4 [hp_X] in 1 mL
ZANTHOXYLUM AMERICANUM BARK (UNII: A4KL1HMZ7T) (ZANTHOXYLUM AMERICANUM BARK - UNII:A4KL1HMZ7T)	ZANTHOXYLUM AMERICANUM BARK	4 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
ATROPA BELLADONNA WHOLE (UNII: DSV74G1P2J) (ATROPA BELLADONNA WHOLE - UNII:DSV74G1P2J)	ATROPA BELLADONNA WHOLE	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
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	12 [hp_X] in 1 mL
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	PHOSPHORIC ACID	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:43857-0168-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	09/28/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/16/2013	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0168) , api manufacture(43857-0168) , label(43857-0168) , pack(43857-0168)