

VITALIZER- echinacea (angustifolia), iodium, arsenicum album, aurum metallicum, calcarea fluorica, gallicum acidum, hekla lava, niccolum sulphuricum, phosphorus, sedum acre, sempervivum tectorum, senecio aureus, blatta americana, onosmodium virginianum 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:

Echinacea 3X, Iodium 6X, Arsenicum Album 12X, Aurum Metallicum 12X, Calcarea Fluorica 12X, Gallicum Acidum 12X, Hekla Lava 12X, Niccolum Sulphuricum 12X, Phosphorus 12X, Sedum Acre 12X, Sempervivum Tectorum 12X, Senecio Aureus 12X, Blatta Americana 16X, Onosmodium Virginianum 30C.

PURPOSE:

For temporary relief of fatigue, weakness after exhausting diseases, headaches and sensitivity to light and noise.

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:

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.

INDICATIONS:

For temporary relief of fatigue, weakness after exhausting diseases, headaches and sensitivity to light and noise.

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

VITALIZER

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:

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

VITALIZER HOMEOPATHIC

ACTIVE INGREDIENTS:

Echinacea 3X, Iodium 6X, Arsenicum Alb 12X, Aur Met 12X, Calc Fluor 12X, Gallicum Ac 12X, Hekla 12X, Niccolum Sulph 12X, Phos 12X, Sedum 12X, Sempervivum 12X, Senecio Aur 12X, Blatta Am 16X, Onosmodium Virginianum 30C.

INACTIVE INGREDIENTS:

Demineralized Water,
25% Ethanol

1 FL OZ (30 ml)

INDICATIONS:

For temporary relief of fatigue, weakness after exhausting diseases, headaches and sensitivity to light and noise.

DIRECTIONS:

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

VITALIZER

echinacea (angustifolia), iodium, arsenicum album, aurum metallicum, calcarea fluorica, gallicum acidum, hekla lava, niccolum sulphuricum, phosphorus, sedum acre, sempervivum tectorum, senecio aureus, blatta americana, onosmodium virginianum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0629
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA WHOLE	3 [hp_X] in 1 mL
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	6 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
GOLD (UNII: 79Y1949PYO) (GOLD - UNII:79Y1949PYO)	GOLD	12 [hp_X] in 1 mL
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
GALLIC ACID MONOHYDRATE (UNII: 48339473OT) (GALLIC ACID - UNII:632XD903SP)	GALLIC ACID MONOHYDRATE	12 [hp_X] in 1 mL
HEKLA LAVA (UNII: C21158IIRK) (HEKLA LAVA - UNII:C21158IIRK)	HEKLA LAVA	12 [hp_X] in 1 mL
NICKEL SULFATE HEXAHYDRATE (UNII: JC9WZ4FK68) (NICKEL CATION - UNII:OIS2CXW7AM)	NICKEL SULFATE HEXAHYDRATE	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
SEDUM ACRE WHOLE (UNII: 2496VW6S9J) (SEDUM ACRE - UNII:2496VW6S9J)	SEDUM ACRE WHOLE	12 [hp_X] in 1 mL
SEMPERVIVUM TECTORUM LEAF (UNII: 3DGJ7BUA01) (SEMPERVIVUM TECTORUM LEAF - UNII:3DGJ7BUA01)	SEMPERVIVUM TECTORUM LEAF	12 [hp_X] in 1 mL
PACKERA AUREA WHOLE (UNII: 5WS1632J8W) (PACKERA AUREA - UNII:5WS1632J8W)	PACKERA AUREA WHOLE	12 [hp_X] in 1 mL
PERIPLANETA AMERICANA (UNII: 2RQ1L9N089) (PERIPLANETA AMERICANA - UNII:2RQ1L9N089)	PERIPLANETA AMERICANA	16 [hp_X] in 1 mL
ONOSMODIUM VIRGINIANUM (UNII: 604NK4250S) (ONOSMODIUM VIRGINIANUM - UNII:604NK4250S)	ONOSMODIUM VIRGINIANUM	30 [hp_C] 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:43857-0629-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/06/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/06/2023	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0629) , api manufacture(43857-0629) , label(43857-0629) , pack(43857-0629)

Revised: 4/2023

BioActive Nutritional, Inc.