

EAR- baptisia tinctoria, echinacea (angustifolia), hydrastis canadensis, phytolacca decandra, capsicum annuum, chamomilla, ferrum phosphoricum, kali muriaticum, plantago major, pulsatilla (vulgaris) 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:

Baptisia Tinctoria 3X, Echinacea (Angustifolia) 3X, Hydrastis Canadensis 3X, Phytolacca Decandra 3X, Capsicum Annuum 12X, Chamomilla 12X, Ferrum Phosphoricum 12X, Kali Muriaticum 12X, Plantago Major 12X, Pulsatilla (Vulgaris) 12X.

INDICATIONS:

For temporary relief of mild earache with soreness, sticking pain in ears, and minor swelling of the ear with redness

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 mild earache with soreness, sticking pain in ears, and minor swelling of the ear with redness

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

EAR

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

EAR

HOMEOPATHIC

ACTIVE INGREDIENTS:

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EAR

baptisia tinctoria, echinacea (angustifolia), hydrastis canadensis, phytolacca decandra, capsicum annuum, chamomilla, ferrum phosphoricum, kali muriaticum, plantago major, pulsatilla (vulgaris) liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0295
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HWI5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HWI5WU)	BAPTISIA TINCTORIA ROOT	3 [hp_X] in 1 mL
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	3 [hp_X] in 1 mL

GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	3 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	3 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	12 [hp_X] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	12 [hp_X] in 1 mL
FERROSFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	12 [hp_X] in 1 mL
POTASSIUM CHLORIDE (UNII: 660YQ981I0) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	12 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	12 [hp_X] in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	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:43857-0295-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/06/2016	05/05/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/18/2014	05/05/2021

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0295) , api manufacture(43857-0295) , label(43857-0295) , pack(43857-0295)