

**EAR- baptisia tinctoria, echinacea (angustifolia), phytolacca decandra, hydrastis canadensis, capsicum annuum, chamomilla, ferrum phosphoricum, kali muriaticum, plantago major, pulsatilla (pratensis) 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, Capsicum Annuum 12X, Chamomilla 12X, Echinacea (Angustifolia) 3X, Ferrum Phosphoricum 12X, Hydrastis Canadensis 5X, Kali Muriaticum 12X, Phytolacca Decandra 4X, Plantago Major 12X, Pulsatilla (Pratensis) 12X.

PURPOSE:

Baptisia Tinctoria - weakness,** Capsicum Annuum - weakness,** Chamomilla - irritability,** Echinacea (Angustifolia) - headache,** Ferrum Phosphoricum - throbbing pain,** Hydrastis Canadensis - sore throat,** Kali Muriaticum - congested ear,** Phytolacca Decandra - fever,** Plantago Major - pain in ear,** Pulsatilla (Pratensis) - ear discomfort**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

USES:

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

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

WARNINGS:

Sore Throat Warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician.

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.

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 or as directed by a health care professional.
- Consult a health care professional for use in children under 12 years of age.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Distributed by:

BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935

bioactivenutritional.com

1-800-288-9525

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

EAR

HOMEOPATHIC

1 fl. oz. (30 mL)



EAR

HOMEOPATHIC

1 fl. oz. (30mL) 25% Ethanol

Do not use if Tamper Evident seal is broken or missing.

Drug Facts

Active Ingredients	Purpose
Baptisia Tinctoria 3X.....	weakness**
Capsicum Annum 12X.....	weakness**
Chamomilla 12X.....	irritability**
Echinacea (Angustifolia) 3X.....	headache**
Ferrum Phosphoricum 12X.....	throbbing pain**
Hydrastis Canadensis 5X.....	sore throat**
Kali Muriaticum 12X.....	congested ear**
Phytolacca Decandra 4X.....	fever**
Plantago Major 12X.....	pain in ear**
Pulsatilla (Pratensis) 12X...	ear discomfort**

Drug Facts (continued under label)

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 1803 N. Wickham Rd., Melbourne, FL 32935
 bioactivenutritional.com
 1018413416216

PEEL HERE

Drug Facts (continued)

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Warnings (continued)

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Demineralized Water, 25% Ethanol

Questions? 1-800-288-9525

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EAR

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43857-0539
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BAPTISIA TINCTORIA ROOT (UNII: 5EF0HW5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HW5WU)	BAPTISIA TINCTORIA ROOT	3 [hp_X] in 1 mL
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA WHOLE	3 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	4 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	5 [hp_X] in 1 mL
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	12 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA WHOLE	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: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	12 [hp_X] in 1 mL
PLANTAGO MAJOR WHOLE (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR WHOLE	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	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:43857-0539-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/24/2019	

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0539) , api manufacture(43857-0539) , label(43857-0539) , pack(43857-0539)

