

**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.*

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**DRUG FACTS:**

**ACTIVE INGREDIENTS:**

Baptisia Tinctoria 3X, Echinacea (Angustifolia) 3X, Phytolacca Decandra 3X, Hydrastis Canadensis 5X, Capsicum Annuum 12X, Chamomilla 12X, Ferrum Phosphoricum 12X, Kali Muriaticum 12X, Plantago Major 12X, Pulsatilla (Pratensis) 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:**

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  
EAR  
HOMEOPATHIC  
1 FL OZ (30 ml)



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### LOT:

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## EAR

### HOMEOPATHIC

**ACTIVE INGREDIENTS:**  
Baptisia Tinctoria 3X, Echinacea 3X,  
Phytolacca Decandra 4X, Hydrastis  
Canadensis 5X, Capsicum Annuum 12X,  
Chamomilla 12X, Ferrum Phosphoricum  
12X, Kali Muriaticum 12X, Plantago Major  
12X, Pulsatilla 12X.

**INACTIVE INGREDIENTS:**  
Demineralized Water,  
25% Ethanol

**1 FL OZ (30 ml)**

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

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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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>BAPTISIA TINCTORIA ROOT</b> (UNII: 5EF0HW5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HW5WU)	BAPTISIA TINCTORIA ROOT	3 [hp_X] in 1 mL
<b>ECHINACEA ANGUSTIFOLIA WHOLE</b> (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA WHOLE	3 [hp_X] in 1 mL
<b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	4 [hp_X] in 1 mL
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	5 [hp_X] in 1 mL
<b>CAPSICUM</b> (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	12 [hp_X] in 1 mL
<b>MATRICARIA CHAMOMILLA WHOLE</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA WHOLE	12 [hp_X] in 1 mL
<b>FERROSFERRIC PHOSPHATE</b> (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	12 [hp_X] in 1 mL
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	12 [hp_X] in 1 mL
<b>PLANTAGO MAJOR WHOLE</b> (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR WHOLE	12 [hp_X] in 1 mL
<b>PULSATILLA PRATENSIS WHOLE</b> (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	12 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (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)

