

**COUGH SYRUP FORMULA- drosera (rotundifolia), coccus cacti, spongia tosta, belladonna, cuprum aceticum, kali carbonicum, mentha piperita, phosphorus 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:**

Drosera (Rotundifolia) 4X, Coccus Cacti 5X, Spongia Tosta 5X, Belladonna 6X, Cuprum Aceticum 12X, Kali Carbonicum 12X, Mentha Piperita 12X, Phosphorus 12X.

**INDICATIONS:**

For temporary relief of irritable, dry, tickling cough associated with flu, spasmodic cough worse at night & cough with expectorations.

**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:**

**SHAKE WELL.**

1 teaspoon every 2-3 hours, children under 12, 1/2 adult dose.

Consult a physician for use in children under 12 years of age.

**INDICATIONS:**

For temporary relief of irritable, dry, tickling cough associated with flu, spasmodic cough worse at night & cough with expectorations.

## INACTIVE INGREDIENTS:

Demineralized Water, Dextrose, Essential Oil Blend [Anise (Seed), Eucalyptus (Leaf)], Ethanol, 10% Herbal Extracts [Chamomile (Flower), Echinacea Angustifolia (leaf, stem), High Mallow (Flower), Iceland Moss (Whole Plant), Mullein (Leaf), Plantain (Leaf), Red Clover (Flower), Stinging Nettle (Leaf), Thyme (Leaf)], Honey, Natural Cherry Flavor, Natural Mixed Berry Flavor.

## QUESTIONS:

Distributed by:

BioActive Nutritional, Inc.

1803 N. Wickham Rd.

Melbourne, FL 32935

bioactivenutritional.com

## PACKAGE LABEL DISPLAY:

**BioActive Homeopathic**

**COUGH SYRUP FORMULA**

**4 FL OZ (120 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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## COUGH SYRUP FORMULA

### HOMEOPATHIC

#### ACTIVE INGREDIENTS:

Drosera 4X, Coccus 5X, Spongia 5X, Belladonna 6X, Cuprum Acet 12X, Kali Carb 12X, Mentha Pip 12X, Phos 12X.

#### INACTIVE INGREDIENTS:

Demineralized Water, Dextrose, Essential Oil Blend [Anise (Seed), Eucalyptus (Leaf)], Ethanol 10%, Herbal Extracts [Chamomile (Flower), Echinacea Angustifolia (Leaf, Stem), High Mallow (Flower), Iceland Moss (Whole Plant), Mullein (Leaf), Plantain (Leaf), Red Clover (Flower), Stinging Nettle (Leaf), Thyme (Leaf)], Honey, Maltodextrin, Natural Cherry and Mixed Berry Flavorings.

**4 FL OZ (120 ml)**

#### INDICATIONS:

For temporary relief of irritable, dry, tickling cough associated with flu, spasmodic cough worse at night & cough with expectorations.

#### SHAKE WELL.

#### DIRECTIONS:

1 teaspoon every 2-3 hours, children under 12, 1/2 adult dose. Consult a physician for use in children under 12 years of age.

## COUGH SYRUP FORMULA

drosera (rotundifolia), coccus cacti, spongia tosta, belladonna, cuprum aceticum, kali carbonicum, mentha piperita, phosphorus liquid

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:43857-0548 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength                     | Strength          |
|---|---------------------------------------|-------------------|
| <b>DROSER ROTUNDIFOLIA WHOLE</b> (UNII: QR44N9XPJQ) (DROSER ROTUNDIFOLIA WHOLE - UNII:QR44N9XPJQ)                         | DROSER ROTUNDIFOLIA WHOLE             | 4 [hp_X] in 1 mL  |
| <b>PROTORTONIA CACTI</b> (UNII: LZB7TFX1LT) (PROTORTONIA CACTI - UNII:LZB7TFX1LT)   | PROTORTONIA CACTI                     | 5 [hp_X] in 1 mL  |
| <b>SPONGIA OFFICINALIS SKELETON, ROASTED</b> (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID) | SPONGIA OFFICINALIS SKELETON, ROASTED | 5 [hp_X] in 1 mL  |
| <b>ATROPA BELLADONNA</b> (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)   | ATROPA BELLADONNA                     | 6 [hp_X] in 1 mL  |
| <b>CUPRIC ACETATE</b> (UNII: 39M11XPH03) (CUPRIC CATION - UNII:8CBV67279L)  | CUPRIC ACETATE                        | 12 [hp_X] in 1 mL |
| <b>POTASSIUM CARBONATE</b> (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)   | POTASSIUM CARBONATE                   | 12 [hp_X] in 1 mL |
| <b>MENTHA X PIPERITA WHOLE</b> (UNII: 79M2M2UDA9) (MENTHA X PIPERITA WHOLE - UNII:79M2M2UDA9)                             | MENTHA X PIPERITA WHOLE               | 12 [hp_X] in 1 mL |
| <b>PHOSPHORUS</b> (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)   | PHOSPHORUS                            | 12 [hp_X] in 1 mL |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>CHAMOMILE</b> (UNII: FGL3685T2X)                   |          |
| <b>ECHINACEA ANGUSTIFOLIA LEAF</b> (UNII: FS7G8S6PJ8) |          |
| <b>MALVA SYLVESTRIS FLOWER</b> (UNII: 12X9JI52BS)     |          |
| <b>CETRARIA ISLANDICA WHOLE</b> (UNII: BJ7YPN79A1)    |          |
| <b>VERBASCUM THAPSUS LEAF</b> (UNII: ANX0EG34JE)      |          |
| <b>PLANTAGO MAJOR LEAF</b> (UNII: 7DC28K241X)         |          |
| <b>TRIFOLIUM PRATENSE FLOWER</b> (UNII: 4JS0838828)   |          |
| <b>URTICA DIOICA LEAF</b> (UNII: X6M0DRN46Q)          |          |
| <b>THYMUS VULGARIS LEAF</b> (UNII: GRX3499643)        |          |
| <b>HONEY</b> (UNII: Y9H1V576FH)                       |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                       |          |
| <b>ALCOHOL</b> (UNII: 3K9958V90M)                     |          |
| <b>CHERRY</b> (UNII: BUC5I9595W)                      |          |
| <b>BERRY</b> (UNII: FV3431923Z)                       |          |
| <b>ANISE OIL</b> (UNII: 6Y89129C8H)                   |          |
| <b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)              |          |
| <b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)  |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                |          |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:43857-0548-1 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/25/2020           |                    |

## Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic |  | 02/25/2020           |                    |

**Labeler** - BioActive Nutritional, Inc. (624980496)

**Registrant** - Apotheca Company (844330915)

## Establishment

| Name             | Address | ID/FEI    | Business Operations  |
|------------------|---------|-----------|--|
| Apotheca Company |         | 844330915 | manufacture(43857-0548) , api manufacture(43857-0548) , label(43857-0548) , pack(43857-0548) |

Revised: 1/2024

BioActive Nutritional, Inc.