

**SINUTONE- echinacea (angustifolia), hydrastis canadensis, allium cepa, ambrosia artemisiaefolia, arsenicum album, kali bichromicum, nux moschata, pulsatilla (pratensis), sepia, solidago virgaurea liquid Energique, 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:**

**(in each drop):** 11.10% of Allium Cepa 12X, Ambrosia Artemisiaefolia 12X, Arsenicum Album 12X, Hydrastis Canadensis 6X, Kali Bichromicum 12X, Nux Moschata 12X, Pulsatilla (Pratensis) 12X, Sepia 12X, Solidago Virgaurea 12X; 0.10% of Echinacea (Angustifolia) 3X.

### **INDICATIONS:**

May temporarily relieve allergic rhinitis with runny nose, nasal mucus with yellow green discharge, pain and swelling of sinus cavities, and postnasal drip.\*\*

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

### **WARNINGS:**

**If pregnant or breast-feeding,** ask a health 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:**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### **DIRECTIONS:**

Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist for more than 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

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### INACTIVE INGREDIENTS:

Demineralized water, 20% Ethanol.

### QUESTIONS:

Dist. by Energique, Inc.

201 Apple Blvd.

Woodbine, IA 51579 **800-869-8078**

### PACKAGE LABEL DISPLAY:

#### ENERGIQUE

SINCE 1987

#### HOMEOPATHIC REMEDY

#### SINUTONE

**1 fl. oz. (30 ml)**

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LOT: XXXXXX MFD: MM/YY

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**HOMEOPATHIC REMEDY**

**SINUTONE™**

**1 fl. oz. (30 ml) 20% Ethanol**

#### Active Ingredients (in each drop):

11.10% of Allium Cepa 12X, Ambrosia Artemisiaefolia 12X, Arsenicum Album 12X, Hydrastis Canadensis 6X, Kali Bichromicum 12X, Nux Moschata 12X, Pulsatilla 12X, Sepia 12X, Solidago Virgaurea 12X; 0.10% of Echinacea 3X.

#### Inactive Ingredients:

Demineralized water, 20% Ethanol.

**DIRECTIONS:** Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist for more than 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.



### SINUTONE

echinacea (angustifolia), hydrastis canadensis, allium cepa, ambrosia artemisiaefolia, arsenicum album, kali bichromicum, nux moschata, pulsatilla (pratensis), sepia, solidago virgaurea liquid

#### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:44911-0515 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength                | Strength          |
|---|----------------------------------|-------------------|
| <b>ECHINACEA ANGUSTIFOLIA WHOLE</b> (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)               | ECHINACEA ANGUSTIFOLIA WHOLE     | 3 [hp_X] in 1 mL  |
| <b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)   | GOLDENSEAL                       | 6 [hp_X] in 1 mL  |
| <b>ONION</b> (UNII: 492225Q21H) (ONION - UNII:492225Q21H)   | ONION                            | 12 [hp_X] in 1 mL |
| <b>AMBROSIA ARTEMISIIFOLIA WHOLE</b> (UNII: 9W34L2CQ9A) (AMBROSIA ARTEMISIIFOLIA - UNII:9W34L2CQ9A)             | AMBROSIA ARTEMISIIFOLIA WHOLE    | 12 [hp_X] in 1 mL |
| <b>ARSENIC TRIOXIDE</b> (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)                              | ARSENIC TRIOXIDE                 | 12 [hp_X] in 1 mL |
| <b>POTASSIUM DICHROMATE</b> (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)                               | POTASSIUM DICHROMATE             | 12 [hp_X] in 1 mL |
| <b>NUTMEG</b> (UNII: AEE24M3MQ9) (NUTMEG - UNII:AEE24M3MQ9)   | NUTMEG                           | 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 |
| <b>SEPIA OFFICINALIS JUICE</b> (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)                   | SEPIA OFFICINALIS JUICE          | 12 [hp_X] in 1 mL |
| <b>SOLIDAGO VIRGAUREA FLOWERING TOP</b> (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50) | SOLIDAGO VIRGAUREA FLOWERING TOP | 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:44911-0515-1 | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 10/09/2019           |                    |

### Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic |  | 10/09/2019           |                    |

**Labeler** - Energique, Inc. (789886132)

**Registrant** - Apotheca Company (844330915)

## Establishment

| Name             | Address | ID/FEI    | Business Operations  |
|------------------|---------|-----------|--|
| Apotheca Company |         | 844330915 | manufacture(44911-0515) , api manufacture(44911-0515) , label(44911-0515) , pack(44911-0515) |

Revised: 4/2024

Energique, Inc.