GASTROTONE- gentiana lutea, sambucus nigra, arsenicum album, kali bichromicum, lycopodium clavatum, phosphorus, pulsatilla (pratensis), bismuthum subnitricum 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): 16.63% of Arsenicum Album 12X, Bismuthum Subnitricum 15X, Kali Bichromicum 12X, Lycopodium Clavatum 12X, Phosphorus 12X, Pulsatilla (Pratensis) 12X; 0.10% of Gentiana Lutea 3X, Sambucus Nigra 3X.

#### INDICATIONS:

May temporarily relieve indigestion, nausea, retching, vomiting after eating or drinking, and minor burning in the stomach.\*\*

\*\*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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and minor burning in the stomach.\*\*

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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

#### **GASTROTONE**

1 fl. oz. (30 ml)

WARNINGS: If pregnant or breastfeeding, 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.

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LOT: XXXXXX MFD: MM/YY

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## **GASTROTONE**

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#### **Product Information**

| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:44911-0563 |
|-------------------------|----------------|--------------------|----------------|
| Route of Administration | ORAL           |                    |                |

| Active Ingredient/Active Moiety   |                                 |                      |  |  |  |
|---|---------------------------------|----------------------|--|--|--|
| Ingredient Name   | <b>Basis of Strength</b>        | Strength             |  |  |  |
| <b>GENTIANA LUTEA ROOT</b> (UNII: S7203284MS) (GENTIANA LUTEA ROOT - UNII:S7203284MS)                   | GENTIANA LUTEA ROOT             | 3 [hp_X]<br>in 1 mL  |  |  |  |
| <b>SAMBUCUS NIGRA FLOWERING TOP</b> (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U) | SAMBUCUS NIGRA<br>FLOWERING TOP | 3 [hp_X]<br>in 1 mL  |  |  |  |
| <b>ARSENIC TRIOXIDE</b> (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII: C96613F5AV)                     | ARSENIC TRIOXIDE                | 12 [hp_X]<br>in 1 mL |  |  |  |
| POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)                              | POTASSIUM<br>DICHROMATE         | 12 [hp_X]<br>in 1 mL |  |  |  |
| LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)              | LYCOPODIUM<br>CLAVATUM SPORE    | 12 [hp_X]<br>in 1 mL |  |  |  |
| PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)  | PHOSPHORUS                      | 12 [hp_X]<br>in 1 mL |  |  |  |
| <b>PULSATILLA PRATENSIS WHOLE</b> (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)     | PULSATILLA PRATENSIS<br>WHOLE   | 12 [hp_X]<br>in 1 mL |  |  |  |
| <b>BISMUTH SUBNITRATE</b> (UNII: H19J064BA5) (BISMUTH CATION - UNII: ZS9CD1I8YE)                        | BISMUTH SUBNITRATE              | 15 [hp_X]<br>in 1 mL |  |  |  |

| Inactive Ingredients       |  |  |  |
|----------------------------|--|--|--|
| Ingredient Name Strength   |  |  |  |
| WATER (UNII: 059QF0KO0R)   |  |  |  |
| ALCOHOL (UNII: 3K9958V90M) |  |  |  |

| l | Packaging |                      |   |                         |                       |  |
|---|-----------|----------------------|---|-------------------------|-----------------------|--|
|   | #         | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |
|   | 1         | NDC:44911-<br>0563-1 | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 10/13/2020              |                       |  |

| Marketing Information     |   |                         |                       |  |
|---------------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category     | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| unapproved<br>homeopathic |   | 10/13/2020              |                       |  |
| потпеораинс               |   |                         |                       |  |

# Labeler - Energique, Inc. (789886132)

# **Registrant -** Apotheca Company (844330915)

| Establishment |      |         |        |                     |
|---------------|------|---------|--------|---------------------|
|               | Name | Address | ID/FEI | Business Operations |

| Apotheca | 844330015 | manufacture(44911-0563), | api manufacture(44911-0563) , label(44911-0563) , |
|----------|-----------|--------------------------|---|
| Company  | 044330913 | pack(44911-0563)         |   |

Revised: 6/2022 Energique, Inc.