

GASTROTONE- gentiana lutea, sambucus nigra, arsenicum album, kali bichromicum, lycopodium clavatum, phosphorus, pulsatilla (vulgaris), 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.

Drug Facts:

ACTIVE INGREDIENTS:

Gentiana Lutea 3X, Sambucus Nigra 3X, Arsenicum Album 12X, Kali Bichromicum 12X, Lycopodium Clavatum 12X, Phosphorus 12X, Pulsatilla 12X, Bismuthum Subnitricum 15X.

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, 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)

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LOT: XXXXXX

GASTROTONE

gentiana lutea, sambucus nigra, arsenicum album, kali bichromicum, lycopodium clavatum, phosphorus, pulsatilla (vulgaris), bismuthum subnitricum liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0455
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GENTIANA LUTEA ROOT (UNII: S72O3284MS) (GENTIANA LUTEA ROOT - UNII:S72O3284MS)	GENTIANA LUTEA ROOT	3 [hp_X] in 1 mL
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	3 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	12 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	12 [hp_X] in 1 mL
BISMUTH SUBNITRATE (UNII: H19J064BA5) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBNITRATE	15 [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:44911-0455-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/08/2018	11/03/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/08/2018	11/03/2025

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
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Apotheca Company	844330915	manufacture(44911-0455) , api manufacture(44911-0455) , label(44911-0455) , pack(44911-0455)
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Revised: 3/2022

Energique, Inc.