

FLUTONE- baptisia tinctoria, echinacea (angustifolia), phytolacca decandra, hydrastis canadensis, arsenicum album, bryonia (alba), eupatorium perfoliatum, ferrum phosphoricum, gelsemium sempervirens, ipecacuanha, rhus tox. 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:

(in each drop): 11.09% Arsenicum Album 12X, Bryonia (Alba) 12X, Eupatorium Perfoliatum 12X, Ferrum Phosphoricum 12X, Gelsemium Sempervirens 12X, Hydrastis Canadensis 6X, Ipecacuanha 12X, Phytolacca Decandra 4X, Rhus Tox 12X; 0.10% of Baptisia Tinctoria 3X, Echinacea (Angustifolia) 3X.

INDICATIONS:

May temporarily relieve minor aches and pains in muscles and joints, fever with dryness of mucous membranes and dry cough, chilliness, and headaches.

**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 3 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

FLUTONE

1 fl. oz. (30 ml)

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HOMEOPATHIC REMEDY

FLUTONE™

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

Active Ingredients (in each drop):

11.09% of Arsenicum Alb 12X, Bryonia 12X, Eupatorium Perf 12X, Ferrum Phos 12X, Gelsemium 12X, Hydrastis 6X, Ipecac 12X, Phytolacca 4X, Rhus Tox 12X; 0.10% of Baptisia 3X, 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 3 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

LOT: XXXXXX MFD: MM/YY



FLUTONE

baptisia tinctoria, echinacea (angustifolia), phytolacca decandra, hydrastis canadensis, arsenicum album, bryonia (alba), eupatorium perfoliatum, ferrum phosphoricum, gelsemium sempervirens,

ipecacuanha, rhus tox. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0514
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BAPTISIA TINCTORIA ROOT (UNII: 5EF0HW5WU) (BAPTISIA TINCTORIA ROOT - UNII:5EF0HW5WU)	BAPTISIA TINCTORIA ROOT	3 [hp_X] in 1 mL
ECHINACEA ANGUSTIFOLIA WHOLE (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA WHOLE	3 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	4 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	12 [hp_X] in 1 mL
EUPATORIUM PERFOLIATUM FLOWERING TOP (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	12 [hp_X] in 1 mL
FERROSFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	12 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	12 [hp_X] in 1 mL
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	12 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	12 [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:44911-0514-1	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(44911-0514) , api manufacture(44911-0514) , label(44911-0514) , pack(44911-0514)

Revised: 3/2024

Energique, Inc.