

OTOTONE- baptisia tinctoria, echinacea (angustifolia), hydrastis canadensis, phytolacca decandra, belladonna, calcarea carbonica, chamomilla, ferrum phosphoricum, mercurius solubilis, pulsatilla (pratensis) 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): 12.48% of Belladonna 12X, Calcarea Carbonica 12X, Chamomilla 12X, Ferrum Phosphoricum 12X, Hydrastis Canadensis 6X, Mercurius Solubilis 12X, Phytolacca Decandra 6X, Pulsatilla (Pratensis) 12X; 0.10% of Baptisia Tinctoria 3X, Echinacea Angustifolia 3X.

INDICATIONS:

May temporarily relieve mild ear disorders with soreness, sticking pain in ear, and minor swelling of the ear with redness.**

**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 4 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

OTOTONE

1 fl. oz. (30 ml)

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LOT: XXXXXX MFD: MM/YY

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0467
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 (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	3 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	6 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	12 [hp_X] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	12 [hp_X] in 1 mL
FERROSO FERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSO FERRIC PHOSPHATE	12 [hp_X] in 1 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	12 [hp_X] in 1 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	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:44911-0467-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/21/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/21/2018	

Labeler - Energique, Inc. (789886132)

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

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0467) , api manufacture(44911-0467) , label(44911-0467) , pack(44911-0467)

Revised: 2/2022

Energique, Inc.