

RELAXATONE- passiflora incarnata, scutellaria lateriflora, valeriana officinalis, arsenicum album, calcarea carbonica, coffea cruda 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): 14.24% of Arsenicum Album 12X, Calcarea Carbonica 12X, Coffea Cruda 12X, Ignatia Amara 12X, Kali Phosphoricum 12X, Lycopus Virginicus 12X, Staphysagria 12X; 0.10% of Passiflora Incarnata 3X, Scutellaria Lateriflora 3X, Valeriana Officinalis 3X.

INDICATIONS:

May temporarily relieve anxiety and stress.

**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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FDA evaluated.

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

RELAXATONE

2 fl. oz. (60 ml)

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LOT: XXXXXX

RELAXATONE

passiflora incarnata, scutellaria lateriflora, valeriana officinalis, arsenicum album, calcarea carbonica, coffea cruda liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0640
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	3 [hp_X] in 1 mL
SCUTELLARIA LATERIFLORA WHOLE (UNII: 7BP4DH5PDC) (SCUTELLARIA LATERIFLORA WHOLE - UNII:7BP4DH5PDC)	SCUTELLARIA LATERIFLORA WHOLE	3 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	3 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	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
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	12 [hp_X] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	12 [hp_X] in 1 mL
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	12 [hp_X] in 1 mL
LYCOPUS VIRGINICUS (UNII: TWH5125Q6F) (LYCOPUS VIRGINICUS - UNII:TWH5125Q6F)	LYCOPUS VIRGINICUS	12 [hp_X] in 1 mL
DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	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:44911-0640-1	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	06/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/22/2021	

Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0640) , api manufacture(44911-0640) , label(44911-0640) , pack(44911-0640)

Revised: 6/2021

Energique, Inc.