

BREATHTONE- lobelia inflata, verbascum thapsus, balsamum peruvianum, antimonium tartaricum, arsenicum album, drosera (rotundifolia), kali bichromicum, kali carbonicum, natrum sulphuricum, phosphorous, spongia tosta 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): 12.46% of Antimonium Tartaricum 12X, Arsenicum Album 12X, Drosera (Rotundifolia) 12X, Kali Bichromicum 12X, Kali Carbonicum 12X, Natrum Sulphuricum 12X, Phosphorous 12X, Spongia Tosta 12X; 0.10% of Balsamum Peruvianum 6X, Lobelia Inflata 3X, Verbascum Thapsus 3X.

INDICATIONS:

May temporarily relieve dry hacking cough, hoarseness, bronchial congestion and hay fever symptoms, and difficulty breathing with tightness of chest from congestion of chest.**

**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.

INDICATIONS:

May temporarily relieve dry hacking cough, hoarseness, bronchial congestion and hay fever symptoms, and difficulty breathing with tightness of chest.**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not 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

BREATHTONE

1 fl. oz. (30 ml)

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.

INDICATIONS: May temporarily relieve dry hacking cough, hoarseness, congestion, shortness of breath, and difficulty breathing with tightness of chest.**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

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HOMEOPATHIC REMEDY

BREATHTONE™

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

Active Ingredients (in each drop):

12.46% of Antimon Tart 12X, Arsenicum Alb 12X, Drosera 12X, Kali Bic 12X, Kali Carb 12X, Nat Sulphuricum 12X, Phos 12X, Spongia 12X; 0.10% of Balsamum 6X, Lobelia Inf 3X, Verbasum 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 7 days, consult your health care professional. Consult a physician for use in children under 12 years of age.

LOT: XXXXXX MFD: MM/YY



BREATHTONE

lobelia inflata, verbasum thapsus, balsamum peruvianum, antimonium tartaricum, arsenicum

album, drosera (rotundifolia), kali bichromaticum, kali carbonicum, natrum sulphuricum, phosphorous, sponsia tosta liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0590
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LOBELIA INFLATA WHOLE (UNII: 9PP1T3TC5U) (LOBELIA INFLATA - UNII:9PP1T3TC5U)	LOBELIA INFLATA WHOLE	3 [hp_X] in 1 mL
VERBASCUM THAPSUS WHOLE (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS WHOLE	3 [hp_X] in 1 mL
BALSAM PERU (UNII: 8P5F881OCY) (BALSAM PERU - UNII:8P5F881OCY)	BALSAM PERU	6 [hp_X] in 1 mL
ANTIMONY POTASSIUM TARTRATE (UNII: DL6OZ476V3) (ANTIMONY CATION (3+) - UNII:069647RPT5)	ANTIMONY POTASSIUM TARTRATE	12 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	12 [hp_X] in 1 mL
DROSERA ROTUNDIFOLIA WHOLE (UNII: QR44N9XPJQ) (DROSERA ROTUNDIFOLIA - UNII:QR44N9XPJQ)	DROSERA ROTUNDIFOLIA WHOLE	12 [hp_X] in 1 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	12 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	12 [hp_X] in 1 mL
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	12 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	12 [hp_X] in 1 mL
SPONGIA OFFICINALIS SKELETON, ROASTED (UNII: 1PIP394IID) (SPONGIA OFFICINALIS SKELETON, ROASTED - UNII:1PIP394IID)	SPONGIA OFFICINALIS SKELETON, ROASTED	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:44911-0590-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/27/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved		05/27/2021	

homeopathic		03/27/2021	
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Labeler - Energique, Inc. (789886132)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0590) , api manufacture(44911-0590) , label(44911-0590) , pack(44911-0590)

Revised: 8/2023

Energique, Inc.