

**GYNESTAT- cimicifuga racemosa, eucalyptus globulus, argentum nitricum, calcarea carbonica, kali bichromicum, kreosotum, mercurius solubilis, pulsatilla (pratensis), sepia, staphysagria, thuja occidentalis 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.*

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**Drug Facts:**

**ACTIVE INGREDIENTS:**

(in each drop): 11.09% of Argentum Nitricum 12X, Calcarea Carbonica 12X, Kali Bichromicum 12X, Kreosotum 12X, Mercurius Solubilis 12X, Pulsatilla (Pratensis) 12X, Sepia 12X, Staphysagria 12X, Thuja Occidentalis 12X; 0.10% of Cimicifuga Racemosa 3X, Eucalyptus Globulus 3X.

**INDICATIONS:**

May temporarily relieve menstrual pain and vaginal irritation.\*\*

\*\*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 menstrual pain and vaginal irritation.\*\*

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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

#### GYNESTAT

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.

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LOT: XXXXXX MFD: MM/YY

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HOMEOPATHIC REMEDY

GYNESTAT™

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

**Active Ingredients (in each drop):**  
11.09% of Arg Nit 12X, Calc Carb 12X, Kali Bic 12X, Kreosotum 12X, Merc Solub 12X, Pulsatilla 12X, Sepia 12X, Staphysag 12X, Thuja Occ 12X; 0.10% of Cimicifuga 3X, Eucalyptus 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.



### GYNESTAT

cimicifuga racemosa, eucalyptus globulus, argentum nitricum, calcarea carbonica, kali bichromicum, kreosotum, mercurius solubilis, pulsatilla (pratensis), sepia, staphysagria, thuja occidentalis liquid

#### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:44911-0279

**Route of Administration** ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BLACK COHOSH</b> (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	3 [hp_X] in 1 mL
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6) (EUCALYPTUS GLOBULUS LEAF - UNII:S546YLW6E6)	EUCALYPTUS GLOBULUS LEAF	3 [hp_X] in 1 mL
<b>SILVER NITRATE</b> (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	12 [hp_X] in 1 mL
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 mL
<b>POTASSIUM DICHROMATE</b> (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	12 [hp_X] in 1 mL
<b>WOOD CREOSOTE</b> (UNII: 3JYG22FD73) (WOOD CREOSOTE - UNII:3JYG22FD73)	WOOD CREOSOTE	12 [hp_X] in 1 mL
<b>MERCURIUS SOLUBILIS</b> (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	12 [hp_X] in 1 mL
<b>PULSATILLA PRATENSIS</b> (UNII: 8E272251DI) (PULSATILLA PRATENSIS - UNII:8E272251DI)	PULSATILLA PRATENSIS	12 [hp_X] in 1 mL
<b>SEPIA OFFICINALIS JUICE</b> (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	12 [hp_X] in 1 mL
<b>DELPHINIUM STAPHISAGRIA SEED</b> (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	12 [hp_X] in 1 mL
<b>THUJA OCCIDENTALIS LEAFY TWIG</b> (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	12 [hp_X] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44911-0279-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/23/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/23/2015	

**Labeler** - Energique, Inc. (789886132)

**Registrant** - Apotheca Company (844330915)

## Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(44911-0279) , api manufacture(44911-0279) , label(44911-0279) , pack(44911-0279)

Revised: 5/2021

Energique, Inc.