

**DENTASTAT- allium sativum, berberis vulgaris, fucus vesiculosus, phytolacca decandra, argentum metallicum, aurum metallicum, calcarea fluorica, calcarea phosphorica, iodium, mercurius solubilis, niccolum metallicum, platinum metallicum, silicea, zincum metallicum 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:**

Allium Sativum 3X, Berberis Vulgaris 3X, Fucus Vesiculosus 3X, Phytolacca Decandra 6X, Argentum Metallicum 12X, Aurum Metallicum 12X, Calcarea Fluorica 12X, Calcarea Phosphorica 12X, Iodium 12X, Mercurius Solubilis 12X, Niccolum Metallicum 12X, Platinum Metallicum 12X, Silicea 12X, Zincum Metallicum 12X.

### **INDICATIONS:**

May temporarily relieve symptoms of associated with dental procedures, such as pain and minor inflammation in the mouth or on the gums.\*\*

\*\*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, consult your health care professional. Consult a physician for use in children under 12 years of age.

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May temporarily relieve symptoms of associated with dental procedures, such as pain and minor inflammation in the mouth or on the gums.\*\*

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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

### DENTASTAT

1 fl. oz. (30 ml)

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HOMEOPATHIC REMEDY

DENTASTAT™

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

**Active Ingredients:** Allium Sat 3X, Berber Vulg 3X, Fucus 3X, Phytolacca 6X, Arg Met 12X, Aur Met 12X, Calc Fluor 12X, Calc Phos 12X, Iodium 12X, Merc Solub 12X, Niccolum Met 12X, Platinum Met 12X, Silicea 12X, Zinc Met 12X.

**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, consult your health care professional. Consult a physician for use in children under 12 years of age.

LOT: XXXXXX

## DENTASTAT

allium sativum, berberis vulgaris, fucus vesiculosus, phytolacca decandra, argentum metallicum, aurum metallicum, calcarea fluorica, calcarea phosphorica, iodium, mercurius solubilis, niccolum metallicum, platinum metallicum, silicea, zincum metallicum liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:449 11-0453
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GARLIC (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)	GARLIC	3 [hp_X] in 1 mL

<b>BERBERIS VULGARIS ROOT BARK</b> (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	3 [hp_X] in 1 mL
<b>FUCUS VESICULOSUS</b> (UNII: 535G2ABX9M) (FUCUS VESICULOSUS - UNII:535G2ABX9M)	FUCUS VESICULOSUS	3 [hp_X] in 1 mL
<b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	6 [hp_X] in 1 mL
<b>SILVER</b> (UNII: 3M4G523W1G) (SILVER - UNII:3M4G523W1G)	SILVER	12 [hp_X] in 1 mL
<b>GOLD</b> (UNII: 79Y1949PYO) (GOLD - UNII:79Y1949PYO)	GOLD	12 [hp_X] in 1 mL
<b>CALCIUM FLUORIDE</b> (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	12 [hp_X] in 1 mL
<b>IODINE</b> (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	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>NICKEL</b> (UNII: 70V03QG267) (NICKEL - UNII:70V03QG267)	NICKEL	12 [hp_X] in 1 mL
<b>PLATINUM</b> (UNII: 49DFR088MY) (PLATINUM - UNII:49DFR088MY)	PLATINUM	12 [hp_X] in 1 mL
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
<b>ZINC</b> (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	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:44911-0453-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/25/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/25/2018	

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

**Registrant** - Apotheca Company (844330915)

### Establishment

Name	Address	ID/FEI	Business Operations
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Apotheca Company		844330915	manufacture(449 11-0453) , api manufacture(449 11-0453) , label(449 11-0453) , pack(449 11-0453)
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Revised: 4/2018

Energique, Inc.