

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

-----  
**DRUG FACTS:**

**ACTIVE INGREDIENTS:**

**(in each drop)** Argentum Metallicum 12X 7.67%, Aurum Metallicum 12X 7.67%, Calcarea Fluorica 12X 7.67%, Calcarea Phosphorica 12X 7.67%, Hekla Lava 12X 7.67%, Hydrofluoricum Acidum 12X 7.67%, Iodium 12X 7.67%, Mercurius Solubilis 12X 7.67%, Niccolum Metallicum 12X 7.67%, Phytolacca Decandra 6X 7.67%, Platinum Metallicum 16X 7.67%, Silicea 12X 7.67%, Zincum Metallicum 12X 7.67%, Allium Sativum 3X 0.10%, Berberis Vulgaris 3X 0.10%, Fucus Vesiculosus 3X 0.10%.

**PURPOSES:**

Argentum Metallicum – bruised pains\*\*, Aurum Metallicum – foul breath\*\*, Calcarea Fluorica – sensitive teeth\*\*, Calcarea Phosphorica – bitter taste\*\*, Hekla Lava – toothache\*\*, Hydrofluoricum Acidum – sore mouth\*\*, Iodium – sweetish taste\*\*, Mercurius Solubilis – metallic taste\*\*, Niccolum Metallicum – stiff tongue\*\*, Phytolacca Decandra – lymphatic congestion\*\*, Platinum Metallicum – tongue pain\*\*, Silicea – dry mouth\*\*, Zincum Metallicum – bleeding gums\*\*, Allium Sativum – swollen gums\*\*, Berberis Vulgaris – thick saliva\*\*, Fucus Vesiculosus – neck swelling\*\*.

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

**USES:**

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

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

**WARNINGS:**

**Stop use and ask a doctor if** symptoms persist for more than 7 days.

**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:**

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.
- Consult a physician for use in children under 12 years of age.

**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)**



**HOMEOPATHIC REMEDY**

**DENTASTAT™**

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

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING

**Drug Facts**

| <b>Active ingredients (in each drop)</b> | <b>Purposes</b>   |
|--|-------------------|
| Arg Met 12X 7.67% .....                  | bruised pains**   |
| Aur Met 12X 7.67% .....                  | foul breath**     |
| Calc Fluor 12X 7.67% .....               | sensitive teeth** |
| Calc Phos 12X 7.67% .....                | bitter taste**    |
| Hekla 12X 7.67% .....                    | toothache**       |
| Hydrofluoricum Ac 12X 7.67% .....        | sore mouth**      |
| Iodium 12X 7.67% .....                   | sweetish taste**  |
| Merc Solub 12X 7.67% .....               | metallic taste**  |
| Niccolum Met 12X 7.67% .....             | stiff tongue**    |



Dist. by Energique, Inc.  
201 Apple Blvd.  
Woodbine, IA 51579  
800.869.8078

NO VARNISH AREA

PEEL HERE

*Drug Facts* (continued under label)

**Drug Facts** (continued)

|                              |                        |
|------------------------------|------------------------|
| Phytolacca 6X 7.67% .....    | lymphatic congestion** |
| Platinum Met 16X 7.67% ..... | tongue pain**          |
| Silicea 12X 7.67% .....      | dry mouth**            |
| Zinc Met 12X 7.67% .....     | bleeding gums**        |
| Allium Sat 3X 0.10% .....    | swollen gums**         |
| Berber Vulg 3X 0.10% .....   | thick saliva**         |
| Fucus 3X 0.10% .....         | neck swelling**        |

**Uses** May temporarily relieve symptoms associated with dental procedures, such as:  
•pain •minor swelling in the mouth or on the gums.\*\*

**Drug Facts** (continued)

**Warnings**

**Stop use and ask a doctor if** symptoms persist for more than 7 days.

**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.

**Directions**

• Adults and children 5 to 10 drops orally, 3

TIEDOWN AREA

TIEDOWN AREA

**Drug Facts** (continued)

times daily or as otherwise directed by a health care professional.  
• Consult a physician for use in children under 12 years of age.

**Other information**

Store in a cool, dry place.

**Inactive ingredients**

Demineralized water, 20% Ethanol.

**Questions? 1-800-869-8078**

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

# DENTASTAT

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

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:44911-0661 |
| <b>Route of Administration</b> | ORAL           |                           |                |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength           | Strength             |
|---|-----------------------------|----------------------|
| <b>GARLIC</b> (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)   | GARLIC                      | 3 [hp_X]<br>in 1 mL  |
| <b>BERBERIS VULGARIS ROOT BARK</b> (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U) | BERBERIS VULGARIS ROOT BARK | 3 [hp_X]<br>in 1 mL  |
| <b>FUCUS VESICULOSUS</b> (UNII: 535G2ABX9M) (FUCUS VESICULOSUS - UNII:535G2ABX9M)                     | FUCUS VESICULOSUS           | 3 [hp_X]<br>in 1 mL  |
| <b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)     | PHYTOLACCA AMERICANA ROOT   | 6 [hp_X]<br>in 1 mL  |
| <b>SILVER</b> (UNII: 3M4G523W1G) (SILVER - UNII:3M4G523W1G)   | SILVER                      | 12 [hp_X]<br>in 1 mL |
| <b>GOLD</b> (UNII: 79Y1949PYO) (GOLD - UNII:79Y1949PYO)   | GOLD                        | 12 [hp_X]<br>in 1 mL |
| <b>CALCIUM FLUORIDE</b> (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)                           | CALCIUM FLUORIDE            | 12 [hp_X]<br>in 1 mL |
| <b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)               | CALCIUM CATION              | 12 [hp_X]<br>in 1 mL |
| <b>HEKLA LAVA</b> (UNII: C21158IIRK) (HEKLA LAVA - UNII:C21158IIRK)                                   | HEKLA LAVA                  | 12 [hp_X]<br>in 1 mL |
| <b>HYDROFLUORIC ACID</b> (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)                          | FLUORIDE ION                | 12 [hp_X]<br>in 1 mL |
| <b>IODINE</b> (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)   | IODINE                      | 12 [hp_X]<br>in 1 mL |
| <b>MERCURIUS SOLUBILIS</b> (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)                 | MERCURIUS SOLUBILIS         | 12 [hp_X]<br>in 1 mL |
| <b>NICKEL</b> (UNII: 7OV03QG267) (NICKEL - UNII:7OV03QG267)   | NICKEL                      | 12 [hp_X]<br>in 1 mL |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)                         | SILICON DIOXIDE             | 12 [hp_X]<br>in 1 mL |
| <b>ZINC</b> (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)   | ZINC                        | 12 [hp_X]<br>in 1 mL |
| <b>PLATINUM</b> (UNII: 49DFR088MY) (PLATINUM - UNII:49DFR088MY)                                       | PLATINUM                    | 16 [hp_X]<br>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:44911-0661-1 | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 10/06/2022           |                    |

## Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic |  | 10/06/2022           |                    |

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

**Registrant** - Apotheca Company (844330915)

## Establishment

| Name             | Address | ID/FEI    | Business Operations  |
|------------------|---------|-----------|--|
| Apotheca Company |         | 844330915 | manufacture(44911-0661) , api manufacture(44911-0661) , label(44911-0661) , pack(44911-0661) |

Revised: 10/2024

Energique, Inc.