

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**, 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:

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)

ENERGIQUE
SINCE 1987

HOMEOPATHIC REMEDY

DENTASTAT™

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING

Active ingredients (in each drop)	Purposes
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**

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Inequ, Inc.
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UNVARNISHED AREA - NO PRIMER

Merc Solub 12X 7.67%..... metallic taste**
 Niccolum Met 12X 7.67% stiff tongue**

Dist. by Energ
 201 Apple Blv
 Woodbine, IA
 800.869.8071

PEEL
 HERE

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

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 and minor swelling in the mouth

Drug Facts (continued)

or on the gums.**

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.

TIEDOWN AREA
 NO TEXT HERE

Drug Facts (continued)

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.

Other information

Store in a cool, dry place.

Inactive ingredients

Demineralized water, 20% Ethanol.

Drug Facts (continued)

Questions? 1-800-869-8078

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

TIEDOWN AREA
 NO TEXT HERE

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44911-0661
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
BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U)	BERBERIS VULGARIS ROOT BARK	3 [hp_X] in 1 mL
FUCUS VESICULOSUS (UNII: 535G2ABX9M) (FUCUS VESICULOSUS - UNII:535G2ABX9M)	FUCUS VESICULOSUS	3 [hp_X] in 1 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	6 [hp_X] in 1 mL
SILVER (UNII: 3M4G523W1G) (SILVER - UNII:3M4G523W1G)	SILVER	12 [hp_X] in 1 mL
GOLD (UNII: 79Y1949PYO) (GOLD - UNII:79Y1949PYO)	GOLD	12 [hp_X] in 1 mL
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	12 [hp_X] in 1 mL
HEKLA LAVA (UNII: C21158IIRK) (HEKLA LAVA - UNII:C21158IIRK)	HEKLA LAVA	12 [hp_X] in 1 mL
HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	12 [hp_X] in 1 mL
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	12 [hp_X] in 1 mL
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	12 [hp_X] in 1 mL
NICKEL (UNII: 7OV03QG267) (NICKEL - UNII:7OV03QG267)	NICKEL	12 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	12 [hp_X] in 1 mL
PLATINUM (UNII: 49DFR088MY) (PLATINUM - UNII:49DFR088MY)	PLATINUM	16 [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:44911-0661-1	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: 9/2022

Energique, Inc.