

**DENTOX- berberis vulgaris, glycyrrhiza glabra, lappa major, stillingia sylvatica, trifolium pratense, phytolacca decandra, lymph node(suis), medulla ossis suis, thymus (suis), thyroidinum (suis), calcarea fluorica, natrum fluoratum, argentum metallicum, aurum metallicum, cuprum metallicum, eugenol, formalinum, lidocaine, mercurius solubilis, molybdenum, niccolum metallicum, palladium metallicum, stannum metallicum, titanium metallicum, zincum metallicum liquid**

**BioActive Nutritional, 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:**

Berberis Vulgaris 3X, Glycyrrhiza Glabra 3X, Lappa Major 3X, Stillingia Sylvatica 3X, Trifolium Pratense 3X, Phytolacca Decandra 4X, Lymph (Suis) 8X, Medulla Ossis Suis 8X, Thymus (Suis) 8X, Thyroidinum (Suis) 8X, Calcarea Fluorica 12X, Natrum Fluoratum 12X, Argentum Metallicum 12X, 30X, 60X, 200X, Aurum Metallicum 12X, 30X, 60X, 200X, Cuprum Metallicum 12X, 30X, 60X, 200X, Eugenol 12X, 30X, 60X, 200X, Formalinum 12X, 30X, 60X, 200X, Lidocaine 12X, 30X, 60X, 200X, Mercurius Solubilis 12X, 30X, 60X, 200X, Molybdenum 12X, 30X, 60X, 200X, Niccolum Metallicum 12X, 30X, 60X, 200X, Palladium Metallicum 12X, 30X, 60X, 200X, Stannum Metallicum 12X, 30X, 60X, 200X, Titanium Metallicum 12X, 30X, 60X, 200X, Zincum Metallicum 12X, 30X, 60X, 200X.

### **PURPOSE:**

For temporary relief of pain and minor inflammation in the mouth or gums following dental procedures.

### **WARNINGS:**

**If pregnant or breast-feeding,** ask a health care 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:**

10 drops orally, 3 times a day. Consult a physician for use in children under 12 years of age.

**INDICATIONS:**

For temporary relief of pain and minor inflammation in the mouth or gums following dental procedures.

**INACTIVE INGREDIENTS:**

Demineralized Water, 25% Ethanol

**QUESTIONS:**

Distributed by:  
BioActive Nutritional, Inc.  
1803 N. Wickham Rd.  
Melbourne, FL 32935  
[bioactivenutritional.com](http://bioactivenutritional.com)

**PACKAGE LABEL DISPLAY:**

**BIOActive Nutritional**

**DENTOX**

**HOMEOPATHIC**

**1 FL OZ (30 ml)**



**WARNINGS:** If pregnant or breast-feeding, ask a health care 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.

**LOT:**

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**DENTOX**  
**HOMEOPATHIC**

**ACTIVE INGREDIENTS:**

Berber Vulg, Glycyrrhiza, Lappa, Stillingia, Trifolium Prat 3X.  
Phytolacca 4X. Lymph Node, Medulla Ossis Suis, Thymus,  
Thyroidinum 8X. Calc Fluor, Nat Fluor 12X. Arg Met, Aur  
Met, Cuprum Met, Eugenol, Formalinum, Lidocaine, Merc  
Solub, Molybdenum, Niccolum Met, Palladium, Stannum  
Met, Titanium, Zinc Met 12X, 30X, 60X, 200X.

**INACTIVE INGREDIENTS:**  
Demineralized Water, 25% Ethanol

**1 FL OZ (30 ml)**

**INDICATIONS:**

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# DENTOX

berberis vulgaris, glycyrrhiza glabra, lappa major, stillingia sylvatica, trifolium pratense, phytolacca decandra, lymph node(suis), medulla ossis suis, thymus (suis), thyroidinum (suis), calcarea fluorica, natrum fluoratum, argentum metallicum, aurum metallicum, cuprum metallicum, eugenol, formalinum, lidocaine, mercurius solubilis, molybdenum, niccolum metallicum, palladium metallicum, stannum metallicum, titanium metallicum, zincum metallicum liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43857-0593
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H) (GLYCYRRHIZA GLABRA - UNII:2788Z9758H)	GLYCYRRHIZA GLABRA	3 [hp_X] in 1 mL
<b>ARCTIUM LAPPA ROOT</b> (UNII: 597E9BI3Z3) (ARCTIUM LAPPA ROOT - UNII:597E9BI3Z3)	ARCTIUM LAPPA ROOT	3 [hp_X] in 1 mL
<b>STILLINGIA SYLVATICA ROOT</b> (UNII: QBR70R4FBK) (STILLINGIA SYLVATICA ROOT - UNII:QBR70R4FBK)	STILLINGIA SYLVATICA ROOT	3 [hp_X] in 1 mL
<b>TRIFOLIUM PRATENSE FLOWER</b> (UNII: 4JS0838828) (TRIFOLIUM PRATENSE FLOWER - UNII:4JS0838828)	TRIFOLIUM PRATENSE FLOWER	3 [hp_X] in 1 mL
<b>PHYTOLACCA AMERICANA ROOT</b> (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	4 [hp_X] in 1 mL
<b>SUS SCROFA LYMPH</b> (UNII: 33A7VYU29L) (SUS SCROFA LYMPH - UNII:33A7VYU29L)	SUS SCROFA LYMPH	8 [hp_X] in 1 mL
<b>SUS SCROFA BONE MARROW</b> (UNII: VP2CN2G7Y8) (SUS SCROFA BONE MARROW - UNII:VP2CN2G7Y8)	SUS SCROFA BONE MARROW	8 [hp_X] in 1 mL
<b>SUS SCROFA THYMUS</b> (UNII: 7B69B0BD62) (SUS SCROFA THYMUS - UNII:7B69B0BD62)	SUS SCROFA THYMUS	8 [hp_X] in 1 mL
<b>THYROID, PORCINE</b> (UNII: 6RV0240AUQ) (SUS SCROFA THYROID - UNII:6RV0240AUQ)	THYROID, PORCINE	8 [hp_X] in 1 mL
<b>CALCIUM FLUORIDE</b> (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	12 [hp_X] in 1 mL
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	12 [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>COPPER</b> (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	12 [hp_X] in 1 mL
<b>EUGENOL</b> (UNII: 3T8H1794QW) (EUGENOL - UNII:3T8H1794QW)	EUGENOL	12 [hp_X] in 1 mL
<b>FORMALDEHYDE SOLUTION</b> (UNII: T0H3L6C7I5) (FORMALDEHYDE SOLUTION - UNII:T0H3L6C7I5)	FORMALDEHYDE SOLUTION	12 [hp_X] in 1 mL
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	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>MOLYBDENUM</b> (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	12 [hp_X] in 1 mL

<b>NICKEL</b> (UNII: 7OV03QG267) (NICKEL - UNII:7OV03QG267)	NICKEL	12 [hp_X] in 1 mL
<b>PALLADIUM</b> (UNII: 5TWQ1V240M) (PALLADIUM - UNII:5TWQ1V240M)	PALLADIUM	12 [hp_X] in 1 mL
<b>TIN</b> (UNII: 387GMG9FH5) (TIN - UNII:387GMG9FH5)	TIN	12 [hp_X] in 1 mL
<b>TITANIUM</b> (UNII: D1JT611TNE) (TITANIUM - UNII:D1JT611TNE)	TITANIUM	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: 059QF0KOOR)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43857-0593-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/14/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/14/2023	

**Labeler** - BioActive Nutritional, Inc. (624980496)

**Registrant** - Apotheca Company (844330915)

## Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43857-0593) , api manufacture(43857-0593) , label(43857-0593) , pack(43857-0593)

Revised: 2/2023

BioActive Nutritional, Inc.