

BIOTOX T- bacillus tetani, ledum palustre liquid
The Wellness Center For Research and Education

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:

Bacillus Tetani 30C, 2LM, Ledum Palustre 30C, 2LM.

INDICATIONS:

For symptoms of stiffness, muscle spasms, difficulty swallowing, irritability, excess sweating, anxiety.

WARNINGS:

If you are pregnant or breastfeeding, 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:

5 drops orally 2 or 3 times per day, 5 days per week until symptoms improve, then 3 drops 3 times daily for 3 days per week until symptoms abate. Consult a physician for use in children under 12 years of age.

INDICATIONS:

For symptoms of stiffness, muscle spasms, difficulty swallowing, irritability, excess sweating, anxiety.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Organic Ethanol

QUESTIONS:

MFD FOR:

The Wellness Center for Research
and Education, Inc.

1237 S. Victoria Ave. Suite 169
Oxnard, CA 93035

PACKAGE LABEL DISPLAY:

Dr. Theresa Dale's

NDC 50181-0058-1

Homeopathic

BioTox

T

1 fl oz (30 ml)

Dr. Theresa Dale's

<p>ACTIVE INGREDIENTS: Bacillus Tetani 30C, 2LM, Ledum Palustre 30C, 2LM.</p> <p>INDICATIONS: For symptoms of stiffness, muscle spasms, difficulty swallowing, irritability, excess sweating, anxiety.</p> <p>MFD FOR: The Wellness Center for Research and Education, Inc. 1237 S. Victoria Ave. Suite 169 Oxnard, CA 93035</p> <p>LOT: XXXXXX</p>	<p>NDC: 50181-0058-1</p> <p>Homeopathic</p> <p>BioTox</p> <p>T</p>  <p>INACTIVE INGREDIENTS: Demineralized Water, 25% Organic Ethanol</p>	<p>DIRECTIONS: 5 drops orally 2 or 3 times per day, 5 days per week until symptoms improve, then 3 drops 3 times daily for 3 days per week until symptoms abate. Consult a physician for use in children under 12 years of age.</p> <p>WARNINGS: If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of over- dose, 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.</p>
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1 fl oz (30 ml)

BIOTOX T			
bacillus tetani, ledum palustre liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50181-0058
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOSTRIDIUM TETANI (UNII: 751E8J54VM) (CLOSTRIDIUM TETANI - UNII:751E8J54VM)	CLOSTRIDIUM TETANI	30 [hp_C] in 1 mL
RHODODENDRON TOMENTOSUM LEAFY TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWG - UNII:877L01IZ0P)	RHODODENDRON TOMENTOSUM LEAFY TWG	30 [hp_C] 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:50181-0058-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/27/2018	

Labeler - The Wellness Center For Research and Education (832363993)**Registrant** - Apotheca Company (844330915)**Establishment**

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(50181-0058) , api manufacture(50181-0058) , label(50181-0058) , pack(50181-0058)

Revised: 6/2021

The Wellness Center For Research and Education