

**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.*

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**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><b>ACTIVE INGREDIENTS:</b> Bacillus Tetani 30C, 2LM, Ledum Palustre 30C, 2LM.</p> <p><b>INDICATIONS:</b> For symptoms of stiffness, muscle spasms, difficulty swallowing, irritability, excess sweating, anxiety.</p> <p><b>MFD FOR:</b> The Wellness Center for Research and Education, Inc. 1237 S. Victoria Ave. Suite 169 Oxnard, CA 93035</p> <p><b>LOT: XXXXXX</b></p>	<p><b>NDC: 50181-0058-1</b></p> <p><b>Homeopathic</b></p> <p><b>BioTox</b></p> <p><b>T</b></p>  <p><b>INACTIVE INGREDIENTS:</b> Demineralized Water, 25% Organic Ethanol</p>	<p><b>DIRECTIONS:</b> 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><b>WARNINGS: If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> 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)**



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

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CLOSTRIDIUM TETANI</b> (UNII: 751E8J54VM) (CLOSTRIDIUM TETANI - UNII:751E8J54VM)	CLOSTRIDIUM TETANI	30 [hp_C] in 1 mL
<b>RHODODENDRON TOMENTOSUM LEAFY TWIG</b> (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWG - UNII:877L01IZ0P)	RHODODENDRON TOMENTOSUM LEAFY TWG	30 [hp_C] 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:50181-0058-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/27/2018	06/04/2026

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/27/2018	06/04/2026

**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: 5/2025

The Wellness Center For Research and Education