

**DENTICALM- topical analgesic emulsion**  
**NFUSE LLC**

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**DentiCalm Massaging Roll On**

**Active Ingredient**

Menthol 2% Purpose: Topical Analgesic

**Usage**

Temporary relief from minor aches and pains of sore muscles and joints associated with teeth grinding and clenching (bruxism)

**Warnings**

For External Use Only

When using this product:

[bullet] Avoid contact with eyes and mucous membranes

[bullet] Do not apply to wounds or broken skin

[bullet] Do not bandage

[bullet] Do not apply to irritated skin or if excessive skin irritation develops

Stop use and ask a doctor if conditions worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

**Keep out of reach of children.**

Keep out of reach of children.

**Directions**

Shake before use. Adults and children 12 years of age and older: apply over affected areas not more than four times daily; massage as necessary. Children under 12 years of age: Consult physician.

**Inactive Ingredients**

Water, Magnesium Chloride USP, Propanediol, PEG-40 Hydrogenated Castor Oil, L-Theanine, Eucalyptus Globulus Leaf Oil, Aloe Barbadensis Leaf Extract, Ilex Paraguariensis Leaf Extract, Boswellia Serrata Oil, Arctium Lappa Root Extract, Thymus Mastichina Flower Oil, 1,2-Hexanediol, Caprylhydroxamic Acid

**Purpose**

Purpose: Topical Analgesic

## Dosage & Administration

Shake before use. Adults and children 12 years of age and older: apply over affected areas not more than four times daily; massage as necessary. Children under 12 years of age: Consult physician.

## Outer Package

**DentiCalm**  
by *nFuse*

**NEW!**

Massage along jawline and neck to:

- Help promote calm & relaxation
- Relieve facial tension
- Relax and relieve sore muscles & joints

**DentiCalm**  
Massaging Glass Roll-On  
Cools & Soothes

Relieves Muscle & Joint Pain

Soothes Aggravated Nerves

Penetrating Tension Relief

**DentiCalm**  
Topical Analgesic Roll-On

Patent Pending

**DentiCalm**  
Topical pain relieving serum with rollerball applicator

**Drug Facts**

Active Ingredient	Purpose
Menthol 2%	Topical Analgesic

**Uses:** Temporary relief from minor aches and pains of sore muscles and joints associated with teeth grinding and clenching (bruxism).

**Warnings**  
For external use only

When using this product

- Avoid contact with eyes or mucous membranes
- Do not apply to wounds or damaged skin
- Do not bandage
- Do not apply to irritated skin or if excessive skin irritation develops

**Stop use and ask a doctor** if conditions worsen, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

**Directions**  
Shake before use. Adults and children 12 years of age and older: apply over affected areas not more than four times daily; massage as necessary. Children under 12 years of age: Consult physician.

**Inactive Ingredients**  
Purified Water, Magnesium Chloride USP, Propylparaben, PEG-40 Hydrogenated Castor Oil, L-Theanine, Eucalyptus Globulus Leaf Oil, Aloe Barbadosensis Leaf Extract, Inositol, Paraguarianis Leaf Extract, Boswellia Serrata Oil, Arctium Lappa Root Extract, Thymus Mastichina Flower Oil, 1,2-Hexanediol, Caprylhydroxamic Acid

Actual Size

For **Clenching & Grinding**  
0.47 FL OZ (14 mL)

**Pain Relief Serum**

Manufactured For:  
Nfuse LLC, PO Box 371 Steersome, MD 21153

NDC 82765-0043-0

## Inner Primary Container Label Front and Back

NDC 82765-0043-1

Directions: Shake well before use. Apply to affected area up to 4 times daily or as directed by dentist. Avoid contact with eyes or damaged skin.  
Mfg. In Warwick, RI Box 371 Swanton, RI 02886 0.47 FL OZ (14 mL)



# DENTICALM

topical analgesic emulsion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82765-0043
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	20 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>PEG-40 CASTOR OIL</b> (UNII: 4ERD2076EF)	
<b>THEANINE</b> (UNII: 8021PR16QO)	
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>BOSWELLIA SERRATA WHOLE</b> (UNII: X7B7P649WQ)	
<b>ARCTIUM LAPP A ROOT OIL</b> (UNII: 55DGS3F5YG)	
<b>THYMUS MASTICHINA FLOWERING TOP OIL</b> (UNII: 9NP0832457)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82765-0043-0	1 in 1 PACKAGE	02/01/2024	
1	NDC:82765-0043-1	0.47 mL in 1 PACKAGE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/01/2024	

**Labeler** - NFUSE LLC (063593294)

Revised: 2/2024

NFUSE LLC