

DENTICALM- topical analgesic emulsion
NFUSE LLC

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.

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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 82765-0002-0

Inner Primary Container Label Front and Back

NDC 82765-0002-1

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82765-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82765-0002-0	1 in 1 PACKAGE	02/01/2024	
1	NDC:82765-0002-1	0.47 mL in 1 APPLICATOR; 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)