

RE-LEVE FOOTLUBE PAIN RELIEF- menthol gel
SOMBRA COSMETICS INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Re-LEVE Footlube Pain Relief

Active Ingredients

Menthol USP 3%

Purpose

Purpose
External Analgesic

Keep out of the reach of children

Keep out of the reach of children

Uses

Detoxifies joints, relieves sore feet, athletes foot, foot odor, perspiration and coldness. Soothes and relieves pain after long hours of standing on feet.

Warnings

Keep out of the reach of children. For external use only. Avoid contact with eyes and mucous membranes, wounds or damaged skin. Store at room temperature. Do not use with heating pads. If symptoms do not respond within one week, see doctor. ReLEVE Products makes no medical claims.

Directions

Apply before putting on socks and shoes.

Inactive Ingredients

Purified water, Carbomer, Yellow #5 Colorant, Blue #1 Colorant, Hamamelis Viriniana Leaf Extract, Yucca Schidigera Stem/Root Extract, Citrus Grandis (Grapefruit) Seed Extract, Decyl Glucoside, Vegetable Glycerin, Aloe Barbadensis Leaf Juice, Emu Oil, Simmondsia Chinensis (Jojoba) Seed oil, Phenoxyethanol, Germanium oil, Caprylyl Glycol, Sodium Carbonate.

Questions or Comments?

Call Toll Free: 1-866-673-5383, 6070 S. Eastern Ave. Suite 210, Las Vegas, NV 89119,
www.reskincare.com

label

RéTM
PRODUCTS, INC.

GET YOUR BODY MOVING![®]

-LEVETM
FOOTLUBE

ALL NATURAL
PAIN RELIEVING FORMULA

Enriched with

- o Geranium Oil
- o Emu Oil

Net Wt. 4 fl oz. 118 ml

RéTM
PRODUCTS, INC.

Footlube is a pain relieving product
enriched with Geranium oil and Emu oil.

Alcohol Free Product NDC 61577-5043-04

Active Ingredients: Menthyl USP 3%

Indications: Detaches joints, relieves sore feet, athlete's foot, foot odor, perspiration and coldness. Soothes and relieves pain after long hours of standing on the feet.

Caution: Keep out of the reach of children. For external use only. Avoid contact with eyes and mucous membranes, wounds or damaged skin. Store at room temperature. Do not use with heating pads. If symptoms do not respond within one week, see your doctor. RéTM Products make no medical claims.

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Questions? Comments? Orders:
Call Toll Free: 1-866-6-RELEVE (1-866-673-5383)
Made in USA
Manufactured for RéTM Products, Inc.
6070 S. Eastern Ave., Suite 210, Las Vegas, NV 89119
www.reskincare.com

This product is not intended to diagnose, treat, cure or prevent any disease.

RE-LEVE FOOTLUBE PAIN RELIEF

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-5042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WITCH HAZEL (UNII: 101I4J0U34)	
YUCCA SCHIDIGERA STEM (UNII: N59C6T6D72)	
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EMU OIL (UNII: 344821WD61)	
JOJOBA OIL (UNII: 724GKU717M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-5042-5	118 g in 1 TUBE; Type 0: Not a Combination Product	11/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/28/2022	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-5042) , label(61577-5042)

Revised: 11/2022

SOMBRA COSMETICS INC.