

THERAPAIN PLUS- menthol roll-on liquid
Tropical Enterprises International, 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.

THERAPAIN PLUS

Active Ingredient

Natural L-menthol 2%

Purpose

Topical Analgesic

Uses:

Relieves temporary pains due to:

- Arthritis
- Stiffness
- Sprains and Strains
- Neck and barckaches
- Muscle Soreness
- Cramps

Warnings:

FOR EXTERNAL USE ONLY

Flammable, Avoid

- heat
- sparks
- open flame

When using this product

- Avoid contact with eyes, mouth, genitalia, mucous membrane, irritated and very sensitive skin
- Do not apply to open wounds or damaged skin.
- Do not bandage tightly.
- Do not. use if you are diabetic or have impaired circulation

Stop use and ask a doctor if

- Excessive skin irritation develops
- Condition worsens.
- Symptoms persist more than 7 days, discontinue use of this product and consult a doctor

KEEP OUT OF REACH OF CHILDREN

Directions:

- Shake well

- Roll-on liberally to affected area not more than 3 to 4 times daily. Wash hands with soap and water after applying.
- Children under 12 years of age: consult a physician.
- After first coat absorbs into skin, re-apply 1-3 extra coats to increase effectiveness.
- Formula dries quickly and won't stain clothes or leave skin lingering with an unpleasant medicine scent.

Other ingredients

Deionized Water, Isopropyl Alcohol, Methyl Sulfonyl Methane (MSM)**,
 Glucosamine Sulfate**, Oil of Peppermint, Oil of Eucalyptus,

****For Use as a Skin Conditioner**

Questions or Comments:

Call toll free: 800-667-1969

Relief-Mart, Inc.

28505 Canwood St. Ste. C

Agoura Hills, CA 93101

www.TherapainPlus.com

Therapain Plus

NATURAL MENTHOL ROLL-ON PLUS GLUCOSAMINE & MSM

ROLL IT ON AND THE PAIN IS GONE!

- ▶ Arthritis
- ▶ Neck & Back Aches
- ▶ Joint Stiffness
- ▶ Muscle Pain

ADVANCED, GREASELESS TOPICAL ANALGESIC, FOR PROMPT, PENETRATING PAIN RELIEF.

CAUTION:
 Flammable Liquid
 Cautions on back label
 3 FL. Oz. (88.5ml) Topical Analgesic

DRUG FACTS

Active ingredient	Purpose
Natural L-menthol 2%	Topical Analgesic

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 • Forr cloth unph

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THERAPAIN PLUS
 menthol roll-on liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-827
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Product Characteristics

Color	white (lotion)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-827-03	88.5 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	08/25/2023	

Labeler - Tropical Enterprises International, Inc. (091986179)**Registrant** - Tropical Enterprises International, Inc. (091986179)**Establishment**

Name	Address	ID/FEI	Business Operations
Tropical Enterprises International, Inc.		091986179	manufacture(58418-827)

Revised: 8/2023

Tropical Enterprises International, Inc.