

PAIN RELIEF GEL-ROLL ON- menthol gel
R & Y Group, LLC

TheraICE™, Menthol, PAIN RELIEF Gel-Roll On, 2.5 fl. oz / 74 mL, Bottle, Gel;
1 bottle each Bag & 3 bottles each Bag

Active Ingredient

Menthol 4.0% w/w Purpose: Topical Analgesic

Purpose

Topical Analgesic

Uses

■ For temporary relief of minor aches and pains of muscles and joints

Warnings

For External Use Only

Flammable: Keep away from excessive heat or open flame

Ask a doctor before use if you have: Sensitive skin

When using this product

■ Avoid contact with eyes or mucous membranes ■ Do not apply to wounds or damaged skin ■ Do not use with other ointments, creams, sprays or liniments ■ Do not apply to irritated skin or if excessive irritation develops ■ Do not bandage ■ Wash hands after use with cool water ■ Do not use with heating pad or device ■ Store in a cool dry place

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur

If pregnant or breast-feeding

ask a health professional before use

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

■ Adults and children 12 years of age and older:

Rub a thin film over affected areas not more than 4 times daily; massage not necessary

■ Children under 12 years of age: Consult Physician

Inactive Ingredients

Alcohol, Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Boswellia Carterii Resin Extract, Camellia Sinensis Leaf Extract, Carbomer, Camphor, FD&C Blue 1, FD&C Yellow 5, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Myristate, Silica, Triethanolamine, Vitamin E, Water

www.theraice.com

Bottle label:

TheraICE®

PAIN RELIEF GEL-ROLL ON
COOLING MENTHOL PAIN RELIEF

TOPICAL ANALGESIC
MENTHOL 4%

- FAST ACTING
- EASY TO APPLY
- NO MESS ROLL-ON
- FOR TEMPORARY PAIN RELIEF

2.5 fl oz (74 mL) Roll-On

TI-MENTHOL4-RO-1PK

SHAKE WELL BEFORE EACH USE
MADE IN CHINA

SUSAN G. KOMEN
Proud Supporter Of
In 2021-2026, TheraICE, LLC will donate to Susan G. Komen \$50,000 regardless of sales. Consumer action will not result in additional donation to Komen. Together, we can end breast cancer.
www.komen.org

Manufactured for:
R&Y Group LLC
20264 NE 15 Ct.,
Miami, FL 33179
www.theraice.com

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COLD THERAPY PAIN RELIEF FOR SORE MUSCLES, BACKACHES, SORE JOINTS AND ARTHRITIS
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

Active Ingredient	Purpose
Menthol 4%	Topical Analgesic

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No Animal Testing • Does not contain NS/AIDs, Ibuprofen, Aspirin or Salicylate

Bag (1 bottle) label:





**COLD THERAPY PAIN RELIEF FOR SORE MUSCLES,
BACKACHES, SORE JOINTS AND ARTHRITIS**
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

Drug Facts

Active Ingredient

Menthol 4%.....Topical Analgesic

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X003Y8HVHB

TheraICE Pain Relief Roll-On™, Knee, Elbow & Calf
New



LOT

FOLLOW US!

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 Miami, FL 33179
www.theraice.com
MADE IN CHINA



Proud Supporter Of **susan g. komen.**
 In 2021-2026, TheraICE, LLC will donate to Susan G. Komen \$50,000 regardless of sales. Consumer action will not result in additional donation to Komen.
 Together, we can end breast cancer.
www.komen.org

2.5 fl oz (74 mL) Roll-On

**FOR TEMPORARY PAIN RELIEF OF:
 SORE JOINTS & MUSCLES • BACKACHES •
 SPRAINS • BRUISES • ARTHRITIS**

• NO MESS ROLL-ON

PAIN RELIEF
GEL-ROLL ON
COOLING MENTHOL PAIN RELIEF

TheraICE[®]



TOPICAL
ANALGESIC
MENTHOL 4%

- FAST ACTING
- EASY TO APPLY





Bag (3 bottles) label:



TheraCE®



3 PK

PAIN RELIEF GEL-ROLL ON
COOLING MENTHOL PAIN RELIEF



TOPICAL ANALGESIC
MENTHOL 4%

- FAST ACTING
- EASY TO APPLY
- NO MESS ROLL-ON

FOR TEMPORARY PAIN RELIEF OF:
SORE JOINTS & MUSCLES • BACKACHES •
SPRAINS • BRUISES • ARTHRITIS

2.5 FL OZ / 74 mL each
3 ROLL-ONS

BACKACHES, SORE JOINTS AND ARTHRITIS
LONG-LASTING • VANISHING SCENT • PARABEN-FREE

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New
TheraICE Pain Relief Roll On...mstring, Knee, Elbow & Calf
X003Y8623Z


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PAIN RELIEF GEL-ROLL ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83016-331
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.04 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL 95% (UNII: 7528N5H79B)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83016-331-	1 in 1 Pkg	10/27/2022	

1	11	1 in 1 BAG	10/27/2023	
1	NDC:83016-331-01	74 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:83016-331-21	3 in 1 BAG	11/01/2023	
2	NDC:83016-331-01	74 mL in 1 BOTTLE; 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	10/27/2023	

Labeler - R & Y Group, LLC (968585765)

Registrant - Shanghai Chuangshi Medical Technology (Group) Co., Ltd. (546872672)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Chuangshi Medical Technology (Group) Co., Ltd.		546872672	manufacture(83016-331)

Revised: 11/2023

R & Y Group, LLC