

THERA PLUS COLD THERAPY PAIN RELIEVING MENTHOL- menthol gel
Fourstar Group USA, Inc.

Thera Plus Cold Therapy Pain Relieving Gel Menthol

Drug Facts

Active ingredient

Menthol 4%

Purpose

Pain Relieving Gel

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: • simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only.

Flammable:Keep away from excessive heat or open flame

When using this product

- use only as directed
- avoid contact with the eyes or on mucous membranes
- do not apply to wounds or damaged skin
- do not apply to irritated skin or if excessive irritation develops
- do not bandage tightly or use with heating pad or device

Stop use and ask a doctor if

- you experience pain, swelling or blistering of the skin
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- arthritic pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age

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 right away.

Directions

- adults and children 2 years of age and older; rub a thin film over affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician
- wash hands after use with cool water

Other information

- store at 20° - 25°C (68° - 77°F)
- store in a cool dry place away from direct sunlight

Inactive ingredients

aloe barbadensis leaf juice, arctium lappa extract, arnica montana flower extract, blue1, boswellia serrata extract, calendula officinalis flower extract, camellia sinensis leaf extract, camphor, carbomer, glycerin, ilex paraguariensis leaf extract, isopropyl alcohol, isopropyl myristate, melissa officinalis leaf extract, methyl methacrylate crosspolymer, tocopheryl acetate, triethanoamine, yellow 5, water

Questions or comments?

1-800-639-3803 Weekdays 9 AM to 4 PM EST

Package Labeling:



Label: 0.75inch

THERA Plus® Cold Therapy Pain Relieving Gel



Cold Therapy
Pain Relieving Gel



COMPARES TO ACTIVE
INGREDIENT IN BIO-FREEZE®
PAIN RELIEF ROLL-ON*

Cold Therapy Pain Relieving Gel

Menthol 4%

No Mess Roll-on Applicator

- For arthritis, backache, joint pain, and muscle pain
- Fast-acting cooling muscle relief



2.5 FL OZ
(74 mL)

THERA Plus®
Cold Therapy
Pain Relieving Gel
Menthol 4%
No Mess Roll-on Applicator

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No Mess Roll-on Applicator

*BioFreeze® is a registered trademark of Biofreeze IP Holdings, LLC. All trademarks and registered trademarks are the property of their respective owners. TheraPlus® is not manufactured or distributed by Biofreeze IP Holdings, LLC.



MANUFACTURED FOR:
FOURSTAR GROUP USA, INC.
925 GRANT ST., AKRON, OH 44311 USA
MADE IN CHINA

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MANUFACTURED FOR: FOURSTAR GROUP USA, INC.
925 GRANT ST., AKRON, OH 44311 USA MADE IN CHINA

THERA PLUS COLD THERAPY PAIN RELIEVING MENTHOL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80684-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80684-101-00	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2024	

Marketing Information

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

Labeler - Fourstar Group USA, Inc. (140099503)

Revised: 11/2023

Fourstar Group USA, Inc.