

THERA PLUS COOL AND HEAT PAIN RELIEVING GEL MENTHOL- menthol liquid
Fourstar Group USA, Inc.

Thera Plus Cool & Heat Pain Relieving Gel Menthol

Drug Facts

Active ingredient

Menthol 16%

Purpose

Topical analgesic

Uses

For the temporarily relief of minor aches and pains of muscles and joints associated with: • simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only.

Test on a small patch of skin before applying generously.

Flammable •keep away from fire or flame

When using this product

• use only as directed • avoid contact with the eyes and mucous membranes • do not apply to wounds or damaged skin • do not bandage tightly • do not use with heating pads or other heating devices • if redness is present, discontinue use and consult a doctor • if skin irritation occurs, discontinue use • a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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 12 years of age and older: • apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat if necessary, but no more than 3 to 4 times daily • IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER. Children 12 years or younger: ask a doctor

Other information

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

Inactive ingredients

acrylates/c10-30 alkyl acrylate crosspolymer, capsaicin, glycerin, isopropyl myristate, propylene glycol, sd alcohol, triethanoamine, water

Questions or comments?

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

Package Labeling:



Cool & Heat Pain Relieving Gel



Cool & Heat Pain Relieving Gel



COMPARES TO ACTIVE
INGREDIENT IN ICY HOT®
PAIN RELIEF ROLL-ON*

Cool & Heat Pain Relieving Gel

Menthol 16%

No Mess Roll-on Applicator

- Helps relieve muscle and joint pain
- Fast acting cooling and heating muscle relief



Cool & Heat
Pain Relieving Gel
Menthol 16%
No Mess Roll-on Applicator

2.5 FL OZ
(74 mL)

- Helps relieve muscle and joint pain
- Fast acting cooling and heating muscle relief



Cool & Heat Pain Relieving Gel

Menthol 16%

No Mess Roll-on Applicator



*Icy Hot® is a registered trademark of Chattem, Inc. All trademarks and registered trademarks are the property of their respective owners. TheraPlus® is not manufactured or distributed by Chattem, Inc.



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

Drug Facts

Active ingredient Purpose
Menthol 16%.....Topical analgesic

Uses

For the temporarily relief of minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains

Warnings

For external use only.
Test on a small patch of skin before applying generously.

When using this product ■ use only as directed ■ avoid contact with the eyes and mucous membranes ■ do not apply to wounds or damaged skin ■ do not bandage tightly ■ do not use with heating pads or other heating devices ■ if redness is present, discontinue use and consult a doctor ■ if skin irritation occurs, discontinue use ■ a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Flammable ■ keep away from fire or flame

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 12 years of age and older: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat if necessary, but no more than 3 to 4 times daily ■ IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER. Children 12 years or younger: ask a doctor

Other information

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

Inactive ingredients

acrylates/c10-30 alkyl acrylate crosspolymer, capsaicin, glycerin, isopropyl myristate, propylene glycol, sd alcohol, triethanolamine, water

Questions or comments? 1-800-639-3803

Weekdays 9 AM to 4 PM EST



Cool & Heat Pain Relieving Gel

Menthol 16%

No Mess Roll-on Applicator

- Helps relieve muscle and joint pain
- Fast acting cooling and heating muscle relief

2.5 FL OZ (74 mL)

Drug Facts

Active ingredient	Purpose
Menthol 16%	Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with: ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains

Warnings

For external use only.
Test on a small patch of skin before applying generously.

When using this product ■ use only as directed ■ avoid contact with the eyes and mucous membranes ■ do not apply to wounds or damaged skin ■ do not bandage tightly ■ do not use with heating pads or other heating devices ■ if redness is present, discontinue use and consult a doctor ■ if skin irritation occurs, discontinue use ■ a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Flammable ■ keep away from fire or flame

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 12 years of age and older: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat if necessary, but no more than 3 to 4 times daily ■ IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER. Children 12 years or younger: ask a doctor

Other information

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

Inactive ingredients

acrylates/c10-30 alkyl acrylate crosspolymer, capsaicin, glycerin, isopropyl myristate, propylene glycol, sd alcohol, triethanolamine, water

Questions or comments? 1-800-639-3803 Weekdays 9 AM to 4 PM EST

*Icy Hot® is a registered trademark of Chattem, Inc. All trademarks and registered trademarks are the property of their respective owners. TheraPlus® is not manufactured or distributed by Chattem, Inc.
MANUFACTURED FOR: FOURSTAR GROUP USA, INC.
925 GRANT ST., AKRON, OH 44311 USA MADE IN CHINA

THERA PLUS COOL AND HEAT PAIN RELIEVING GEL MENTHOL

menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80684-097
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CAPSAICIN (UNII: S07O44R1ZM)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80684-097-00	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.