

PAIN RELIEF COLD THERAPY GEL 3 FL OZ- menthol 4% gel gel
SOTAC PHARMACEUTICAL PRIVATE LIMITED

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.

Active Ingredient

Menthol 4%

Purpose

Cooling Pain Relief

Uses

Temporary relief from minor aches and pains of sore muscles and joints associated with •arthritis •backache •strains •sprains

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 the 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

Stop use and ask a doctor if

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

If pregnant or breast-feeding

ask a health professional before use

Keep out of reach of Children.

If accidentally ingested, get medical help or contact a Poison Control Center (1-800-222-1222) immediately

Directions

- **Adults and children 2 years of age and older:** rub a thin film over affected areas not more than 4 times daily, massage not necessary
- **Children under 2 years of age:** consult physician

Other Information

- store in a cool dry place


Inactive ingredients


aloe vera gel, arnica montana flower extract, articum lappa root (burdock) extract, boswellia carterii resin extract, calendula officinalis extract, camellia sinensis (green tea) leaf extract, camphor, carbomer 934, colloidal silicon dioxide, FD&C blue no.1, FD&C yellow no.5, glycerin, ilex paraguariensis leaf extract, isopropyl alcohol, isopropyl myristate, melissa officinalis (lemon balm) leaf extract, purified water, sorbic acid, tocopheryl acetate, triethanolamine

Questions or comments

1-856-357-7321

Pain Relief Cold Therapy Gel 3 FL OZ

 SOTAC PHARMACEUTICALS PVT. LTD. APPROVED A/W Cold Therapy Gel 3 FL OZ	Artwork No.	A/L/SOT/E/001/00	FOR EXPORT		
	Size	40 DIA X 135 MM		■	PANT
	Printout	100%		■	PANT
	Pack Style	3 FL OZ (88.72 mL)		■	BLAC
	Coating	UV			
	Date	27/02/2021			



*Compare to the active ingredient of Biofreeze® Gel


Pain Relief Cold Zone Gel

3 FL OZ (88.72 mL)

4% menthol

- for arthritis, back pain, sore muscles and joints
- soothing menthol
- vanishing scent
- paraben-free

NDC 72351-641-08



7 2 3 5 1 6 4 1 0 3 4

Drug Facts	
Active ingredient	Purpose
Menthol 4%	Cooling Pain Relief
Uses	
• Temporary relief from minor aches and pains of sore muscles and joints associated with • arthritis • backache • strains • sprains	
Warnings	
<i>For external use only</i>	
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 the 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	
Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days, or clear up and recur	
If pregnant or breast-feeding ask a health professional before use	
Keep out of reach of Children If accidentally ingested, get medical help or contact a Poison Control Center (1-800-222-1222) immediately	
Directions	
• Adults and children 2 years of age and older: rub a thin film over affected areas not more than 4 times daily, massage not necessary	
• Children under 2 years of age: consult physician	
Other information • store in a cool dry place	
Inactive ingredients	
aloe vera gel, arnica montana flower extract, articum lappa root (burdock) extract, boswellia carteri resin extract, calendula officinalis extract, camellia sinensis (green tea) leaf extract, camphor, carbomer 934, colloidal silicon dioxide, FD&C blue no. 1, FD&C yellow no. 5, glycerin, ilex paraguayensis leaf extract, isopropyl alcohol, isopropyl myristate, melissa officinalis (lemon balm) leaf extract, purified water, sorbic acid, tocopheryl acetate, triethanolamine	
Questions or comments 1-856-357-7321	

L16# GUU/DRUGS/G/25/2169

Keep cap tightly closed between uses. Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

PAIN RELIEF COLD THERAPY GEL 3 FL OZ

menthol 4% gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72351-641
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARBOMER 934 (UNII: Z135WT9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TROLAMINE (UNII: 9O3K93S3TK)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BRILLIANT BLUE G (UNII: M1ZRX790SI)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBIC ACID (UNII: X045WJ989B)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72351-641-03	88.72 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2021	

Labeler - SOTAC PHARMACEUTICAL PRIVATE LIMITED (876894019)

Establishment

Name	Address	ID/FEI	Business Operations
Sotac Pharmaceutical Private limited		876894019	label(72351-641) , analysis(72351-641) , manufacture(72351-641)

Revised: 12/2022

SOTAC PHARMACEUTICAL PRIVATE LIMITED