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

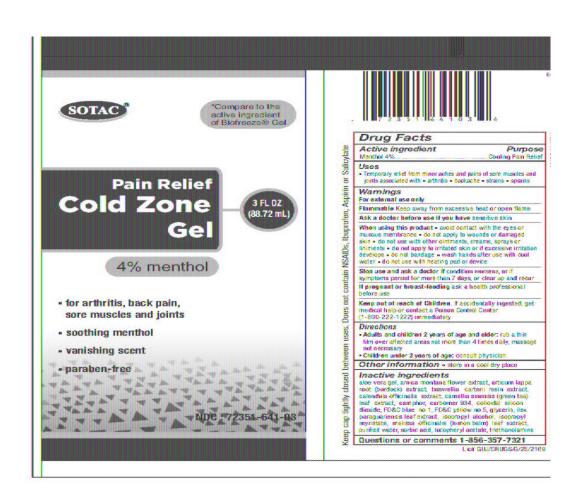
aloe vera gel, arnica montana flower extract, articum lappa root (burdock) extract, boswellia carterii resin extract, calendula officinalis extract, camellia sinensis (green tea) leaf extract, camphor, carbomer 934, colloidal silicon dioxide, FD&C blue no.1, FD&C yellow no.5, glycerin, ilex paraguariensis 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

(\$6n.46)*	Artwork No.	A/L/SOT/E/001/00	FOR EXPORT	u	ISED CO
SUTAC PHARMACEUTICALS PVT. LTD.	Size	40 DIA X 135 MM			PANT
APPROVED A/W	Printout	100%			PANT
Cold Therapy Gel 3 FL 0Z	Pack Style	3 FL OZ (88.72 mL)			BLAC
	Coating	UV			
	Date	27/02/2021			



PAIN RELIEF COLD THERAPY GEL 3 FL OZ

menthol 4% gel gel

Product Information					
Product Type	HUMAN OTC DRUG	Item Co	de (Source)	NDC:72351-641	
Route of Administration TOPICAL					
Active Ingredient/Active Moiety					
Ingredie		Basis of Strengtl	h Strength		

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)				
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: ORE8K4LNJS)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
TROLAMINE (UNII: 903K93S3TK)				
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