COLD ZONE PAIN RELIEVING GEL- DG HEALTH- menthol gel
SOTAC PHARMACEUTICALS 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.

Cold Zone Pain Relieving Gel- DG Health

Active Ingredients

Menthol USP 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 irritated 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 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 with lid closed tightly

Inactive Ingredients

Purified water, Glycerin, Isopropyl alcohol, Iso propyl myristate, Carbopol usp, Aloevera gel, Arnica montana flower extract, Articum lappa root (burdock) extract, Boswellia carterii resin extract, Calendula officinalis extract, Camellia sinensis leaf extract, Iiex paraguariensis leaf extract, Melissa officinalis (lemon balm) leaf extract, Tocopheryl acetate, Triethanolamine, Colloidal silicon dioxide, Sorbic acid, Camphor, Brillient blue, Tartrazin supra

Cold Zone Pain Relieving Gel- DG Health

Lable- Bulk

DG Cold Zone Pain Relief Gel 2 fl oz(59.14 ml)

Active Ingredient
Menthol…….…….…….. Cooling Pain Relief

BATCH NO.		QUANTITY	x 59.14 ml = Tubes
MFG.DATE	06/2018	SHIPPER NO.	--- out of ---
EXP. DATE	05/2020	GROSS WT.	---------- kg.
		NET WT.	---------- kg.

WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY.	STORE AT CONTROLLED TEMPERATURE OF 59°F to 86° F (15 to 30 °C)
CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THERE UNDER	PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING

MANUFACTURED BY:
SOTAC PHARMACEUTICALS PVT LTD
PLOT NO. PF-21, SANAND GIDC-II, CHARAL INDUSTRIAL ESTATE,
TALUKA-SANAND, DISTRICT-AHMEDABAD 382 110. INDIA

Lic# GUJ/DRUGS/G/25/2169	Labeler Code: 72351

SHIPPED TO:
VELOCITY PHARMA LLC
226/B SHERWOOD AVE,
FARMINGDALE , NY-11735

NDC No	72351-001-00
Barcode No.	

COLD ZONE PAIN RELIEVING GEL- DG HEALTH

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72351-001
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
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
BRILLIANT BLUE G (UNII: M1ZRX790SI)	
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ARCTIUM LAPPA WHOLE (UNII: 73070DU1LA)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROLAMINE (UNII: 9O3K93S3TK)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72351-001-00	96 in 1 PACKAGE	04/12/2018	
1		59.14 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/22/2018	

Labeler - SOTAC PHARMACEUTICALS PRIVATE LIMITED (876894019)

Revised: 7/2018 SOTAC PHARMACEUTICALS PRIVATE LIMITED