

COLD AND HEAT PAIN RELIEVING CREAM- menthol and methyl salicylate cream
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 and Heat Pain Relieving Cream

Drug Facts

Active ingredient

Menthol 10%

Methyl salicylate 30%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

For external use only

SEE INSIDE LABEL FOR COMPLETE DRUG FACTS

Allergy Alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- 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 care 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 over 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

ceresin, cyclomethicone, hydrogenated castor oil, microcrystalline wax, paraffin, PEG-150 distearate, propylene glycol, stearic acid, stearyl alcohol (245-111)

PRINCIPAL DISPLAY PANEL

DG Cold 'n Hot Pain Relieving Cream 1.25 oz(35 g)

Active Ingredient
 Menthol 10% Topical analgesic
 Methyl salicylate 30% Topical analgesic

BATCH NO.	MM1801	QUANTITY	00 x 00 x 35 g = 00 Tubes
MFG.DATE	07/2018	SHIPPER NO.	--- out of ---
EXP. DATE	06/2020	GROSS WT.	----- kg.
		NET WT.	----- kg.

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

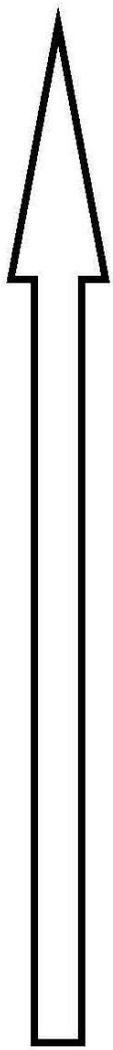
MANUFACTURED BY:
 SOTAC PHARMACEUTICALS PVT LTD
 PLOT NO. PF-21, SANAND GIDC-II, CHARAL INDUSTRIAL ESTATE,
 TALUKA-SANAND, DISTRICT-AHMEDABAD 382 110. INDIA

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

SHIPPED TO:
 VELOCITY PHARMA LLC
 FARMINGDALE , NY-11735

NDC No 76168-402-44

Barcode No.	 3 76168 40244 5
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COLD AND HEAT PAIN RELIEVING CREAM

menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72351-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72351-010-00	208 g in 1 BOX; Type 0: Not a Combination Product	08/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/09/2018	

Labeler - SOTAC PHARMACEUTICALS PRIVATE LIMITED (876894019)

Revised: 8/2018

SOTAC PHARMACEUTICALS PRIVATE LIMITED