

RITE AID ROLL-ON- 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.

Rite Aid Roll-On

Drug Facts

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 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 skin 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 reoccur

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

Inactive Ingredients:

Aloe Vera gel, Camphor, Carbomer, FD&C blue 1, FD&C yellow 5 Glycerol, Isopropyl Alcohol, Isopropyl Myristate, Purified water, Silica, triethanolamine, Tocopheryl (Vitamin E) Acetate,

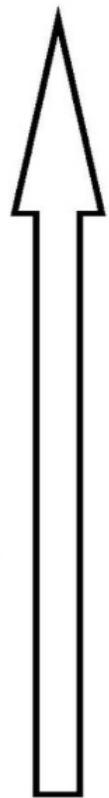
Other Information:

Store in a cool dry place with lid closed tightly

Questions or Comments

1-855-314-1850

RA Cold Therapy Roll On 2.5 fl oz(73 ml)			
Active Ingredient		Menthol 4% Cooling Pain Relief	
BATCH NO.	MR1801	QUANTITY	x 73 ml = Roll On Bottles
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 FARMINGDALE , NY-11735			
NDC No	76168-305-47		
Barcode No.			



RITE AID ROLL-ON
menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72351-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72351-008-00	96 in 1 PACKAGE; 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)