RITE AID ROLL-ON- menthol gel
Velocity Pharma LLC

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, Ispropyl 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

RITE AID ROLL-ON

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-313
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)	
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:76168-313-47	1 in 1 CARTON	07/17/2018	
1		73 mL in 1 BOTTLE, WITH APPLICATOR; 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	07/17/2018	

Labeler - Velocity Pharma LLC (962198409)

Revised: 10/2020 Velocity Pharma LLC