

RITE AID HOT AND COLD EXTRA STRENGTH- menthol, methyl salicylate cream
Rite Aid Corporation

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.

Drug Facts

Active ingredient

Menthol 10%

Methyl salicylate 30%

Purpose

Menthol - Topical analgesic

Methyl salicylate - Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints associated with:

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

Warnings

For external use only

When using this product

- use only as directed
- do not get into eyes or on mucous membranes
- do not apply to wounds or irritated or damaged skin
- do not bandage tightly
- do not use with a heating pad or apply external heat

Stop use and ask a doctor if

- skin redness or excessive irritation of the skin occurs
- condition worsens
- 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 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 12 years and over: apply to affected area not more than 3 to 4 times daily
- children under 12 years: ask a doctor

Inactive Ingredients

glyceryl stearate, isoceteth-20, poloxamer, purified water, sodium lauryl sulfate, sorbitan monostearate, trolamine

Principal Display Panel



RITE AID HOT AND COLD EXTRA STRENGTH

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7958
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	100 mg in 1 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)		METHYL SALICYLATE	300 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
ISOCETETH-20 (UNII: O020065R7Z)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
WATER (UNII: 059QF0KO0R)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)				
TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7958-7	1 in 1 CARTON	06/19/2020	
1		85 g 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	06/19/2020	

Labeler - Rite Aid Corporation (014578892)

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