

RITE AID ULTRA STRENGTH MUSCLE RUB - menthol, camphor, and methylsalicylate ointment
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

Purpose

Camphor 4%.....	External Analgesic
Menthol 10%.....	External Analgesic
Methyl Salicylate 30%.....	External Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache - arthritis - strains - bruises - sprains

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Warnings

For external use only

- avoid contact with eyes and mucous membranes
- do not bandage tightly
- do not use with a heating pad
- do not apply to wounds or damaged skin

Stop use and ask a doctor if condition worsens or symptoms persist for more than 7 days or symptoms clear up and occur again.

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 of age and older**
- apply to affected area not more than 3 to 4 times daily
- **Children under 12 years of age** do not use, ask a doctor.

Other information store at 20 degrees to 25 degrees C (68 degrees to 77 degrees F)

Inactive Ingredients

purified water, stearic acid, glyceryl stearate, PEG-100 stearate, lanolin, triethanolamine, polysorbate 80, carbomer, disodium EDTA, potassium hydroxide



RITE AID ULTRA STRENGTH MUSCLE RUB

menthol, camphor, and methylsalicylate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0406
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	300 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
LANOLIN (UNII: 7EV65EAW6H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0406-4	1 in 1 CARTON		
1		57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/28/2011	

Labeler - RITE AID CORPORATION (014578892)**Registrant** - Pharma Pac, LLC (140807475)**Establishment**

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture