

PAIN RELIEF RUB- camphor,menthol, methyl salicylate cream
Topco Associates 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.

Drug Facts

Active Ingredients

Camphor 4%

Menthol 10%

Methyl Salicylate 30%

Uses

temporarily relieves the minor aches and pains of muscle and joints associated with: simple backache, arthritis, bruises, sprains

For external use only.

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

redness over the affected area

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children to avoid accidental ingestion.

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Use only as directed
- 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: ask a doctor

Other information

- Store at 20° to 25°C (68°to 77°F)

Inactive Ingredients

carbomer940, cetyl alcohol, glyceryl monostearate, isopropyl myristate, polysorbate60, purified water, stearic acid, trolamine

Pain Relief Rub



Topical analgesic

Topical analgesic

Topical analgesic

PAIN RELIEF RUB

camphor,menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-042
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
MENTHYL SALICYLATE, (+/-)- (UNII: 43XOA705ZD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MENTHYL SALICYLATE, (+/-)-	30 g in 100 g
Camphor (Natural) (UNII: N20HL7Q941) (Camphor (Natural) - UNII:N20HL7Q941)	Camphor (Natural)	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-042-04	1 in 1 BOX		
1		114 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2013	

Labeler - Topco Associates LLC (006935977)