TOP MEDICATED - camphor (natural), menthol, methyl salicylate oil A&A Medical Supplies

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.

Top Medicated Oil

Top Medicated Oil

Active Ingredients

Camphor 10%

Menthol 16%

Methyl Salicylate 50%

Purpose

External Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- strains
- bruises
- arthritis
- sprains

Warnings

For external use only

Do not use

- on wounds
- on irritated or damaged skin
- otherwise than as directed

When using this product

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

Stop use and ask a doctor if:

- condition worsens
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

- excessive irritation of the skin develops
- nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs

Keep out of reach of children

IF swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 3 years of age and older:** apply 3 to 4 drops of medicated oil to the affected area 1 to 2 times daily. After applying the product, a warm pad may be placed on the affected area for 10 minutes and then massaged as shown in the illustrations.
- **children under 3 years of age:** consult your physician.
- **refer to the above warnings; use otherwise** than as directed may be dangerous.

Other Information

- store at 16 to 30 degrees C (16 to 86 degrees F)
- preserve in tight container

Inactive Ingredients

- Clove Oil
- Lavender Oil
- Turpentine Oil

Top Medicated Oil 1.7oz/50ml (67473-601-01)





TOP MEDICATED

camphor (natural), menthol, methyl salicylate oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50943-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII: N20 HL7Q941)	CAMPHOR (NATURAL)	10 mL in 100 mL
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	16 mL in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	50 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
CLOVE OIL (UNII: 578389 D6 D0)			
LAVENDER O IL (UNII: ZBP1YXW0H8)			
TURPENTINE O IL (UNII: C5H0 QJ6 V7F)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50943-001-01	50 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part348	05/24/2012		

Labeler - A&A Medical Supplies (801197380)

Registrant - Sheng Chun Tang Pharmaceutical Industrial Co., Ltd. (656347754)

Establishment			
Name	Address	ID/FEI	Business Operations
Sheng Chun Tang Pharmaceutical Industrial Co., Ltd.		656347754	manufacture

Revised: 6/2012 A&A Medical Supplies