

MIRACLE RUB - menthol, methyl salicylate cream

Winning Solutions

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.

Active Ingredient : Menthol , Methyl Salicylate

Purpose : External Analgesic

Warnings : For external use only

Keep Out of Reach of Children : In case of accidental ingestion , get medical help or contact a Poison Control center right away.

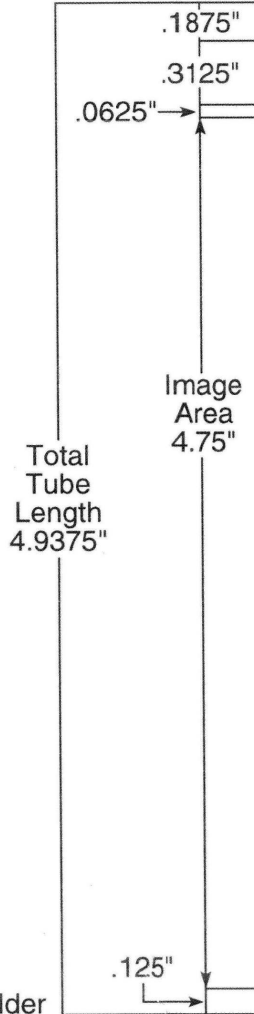
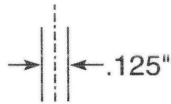
Directions : adults and children 12 years and older ; apply to affected area no more than 3 to 4 times daily

under 12 years: ask a doctor before use

Inactive Ingredients : aloe barbadensis leaf juice , water , stearic acid , cetyl alcohol , glyceryl stearate (and) PEG-100 stearate , petrolatum , dimethicone, triethanolamine , eucalyptus globulus leaf oil , imidazolidinyl urea, methylparaben , propylparaben

Uses : Temporarily relieves minor aches and pains of muscles and joints due to * arthritis * simple backache * strains * sprains * bruises

Top
4.75"





Miracle Rub

Pain Relieving Cream

42% Ultra Aloe™

FAST ACTING RELIEF FOR:

- Arthritis • Muscle Aches
- Sprains • Joint Stiffness

• Fast, soothing pain relief

• Long lasting, non-greasy

• Vanishing scent

Net wt 3.5 oz (99 g)

MIRACLE RUB®

Drug Facts	
Active ingredient	Purpose
Menthol (2.5%)	External Analgesic
Methyl salicylate (10.0%)	External Analgesic
Uses temporarily relieves minor aches and pains of muscles and joints due to ■ arthritis ■ simple backache ■ strains ■ sprains ■ bruises	
Warnings For external use only.	
When using this product ■ use only as directed ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin ■ do not use if skin is sensitive to wintergreen (methyl salicylate) ■ do not bandage tightly or use with a heating pad or apply external heat	
Stop use and ask a doctor if ■ excessive irritation of the skin develops ■ if condition worsens, or if symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days	
If pregnant or breast-feeding, ask a doctor before use	
Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.	
Directions ■ adults and children 12 years and older: apply to affected area no more than 3 to 4 times daily ■ under 12 years: ask a doctor before use	
Inactive ingredients aloe barbadensis leaf juice, water, stearic acid, cetyl alcohol, glyceryl stearate (and) PEG-100 stearate, petrolatum, dimethicone, triethanolamine, eucalyptus globulus leaf oil, imidazolidinyl urea, methylparaben, propylparaben	

CERTIFIED



This product contains 42% pure Aloe Vera gel - **Ultra Aloe™** (aloe barbadensis leaf juice) as certified by the International Aloe Science Council.

Distributed by:
ONTEL PRODUCTS CORP.
Fairfield, NJ 07004
www.ontelproducts.com

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NOT TESTED ON ANIMALS



RE-USE RECYCLE



ENVIRONMENTAL CARE

Made in U.S.A.

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4 oz. Tube

MIRACLE RUB

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66391-0603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.475 g in 99 g

METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y) | METHYL SALICYLATE | 9.9 g in 99 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
Dimethicone (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66391-0603-0	99 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/01/2005	

Labeler - Winning Solutions (962718300)

Registrant - Beautymanufacturing Solutions Corporation (783200723)

Establishment

Name	Address	ID/FEI	Business Operations
Beautymanufacturing Solutions Corporation		783200723	manufacture