

MIRACLE OF ALOE RUB ROLL ON - menthol liquid

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 2.0 %

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 3 years and older ; apply to affected area no more than 3 to 4 times daily

under 3 years: ask a doctor

Inactive Ingredients : water , isopropyl alcohol , aloe barbadensis leaf juice , hydroxyethylcellulose , chamomilla recutita (matricaria) flower , eucalyptus globulus leaf oil , polysorbate 80 , fragrance , methylparaben , dmdm hydantoin

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

4.5 x 3

Drug Facts	
Active ingredient Menthol 2.0%	Purpose External Analgesic
Uses temporarily relieves minor aches and pains of muscles and joints due to ■ arthritis ■ simple backache ■ strains ■ sprains	
Warnings For external use only	
When using this product ■ use only as directed ■ do not get into eyes or mucous membranes ■ do not apply to wounds 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 ■ condition worsens ■ excessive irritation of the skin develops ■ symptoms do not get better within 7 days ■ symptoms clear up and occur again within a few days	
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 3 years and older: apply to affected area no more than 3 to 4 times daily ■ under 3 years: ask a doctor	
Inactive ingredients water, isopropyl alcohol, aloe barbadensis leaf juice, hydroxyethylcellulose, chamomilla recutita (matricaria) flower, eucalyptus globulus leaf oil, polysorbate 80, fragrance, methylparaben, dmdm hydantoin	

CERTIFIED Ultra Aloe™
 This product contains 42% Aloe Vera gel.
 ©2006, Winning Solutions, Inc. Miracle of Aloe® and Ultra Aloe™ are registered trademarks of Jess Clarke & Sons, Inc. All rights reserved. 0606

Product #1950. Distributed by: MIRACLE OF ALOE®
 P.O. Box 612688, Dallas, TX 75261-2688
www.miracleofaloe.com Made in U.S.A.



Temporary, effective relief of

- Minor Muscular Aches and Back Pain
- Arthritis and Painful Joints
- Strains and Sprains

Pain Relieving Liquid
 3 fl oz (90 mL)

MIRACLE OF ALOE RUB ROLL ON			
menthol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66391-0046
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	1.8 mL in 90 mL	
Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)			
CHAMOMILE (UNII: FGL3685T2X)			

CORYMBIA CITRIODORA LEAF OIL (UNII: M63U6N96EB)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
methylparaben (UNII: A218C7H9T)	
dmdm hydantoin (UNII: BYR0546TOW)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66391-0046-0	90 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/17/2006	

Labeler - Winning Solutions (962718300)

Registrant - Beautymanufacturing Solutions Corporation (783200723)

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