

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.

WINNING SOLUTIONS - MIRACLE RUB (66391-1603)

Active Ingredient : Menthol 2.5%

Methylsalicylate 10.0%

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

under 12 years ask a doctor before use

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

- arthritis
- simple backache
- strains
- sprains
- bruises

aloe barabardensis leaf Juice, water, stearic acid, cetyl alcohol, glyceryl stearate, PEG-100 stearte, petrolatum, dimethicone, triethanolamine, eucalyptus globulus leaf oil, imidazolidinyl urea, methylparaben, propylparaben

MIRACLE RUB®
with 42% **Ultra Aloe®**

Provides penetrating, temporary pain relief to tired, aching muscles and joints due to over exertion, arthritis, rheumatism and bursitis.

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
Ultra Aloe®

This product contains 42% Aloe Vera gel (aloe barbadensis leaf juice) by volume.

Product #101. Distributed By:
MIRACLE OF ALOE®
P.O. Box 612688
Dallas, TX 75261-2688

Questions or comments?

Call Consumer Hotline
Toll-Free 1-800-988-2583

www.miracleofaloe.com

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ENVIRONMENTAL
CARING

Made
in U.S.A.



Miracle of Aloe®

Miracle Rub®
Cream

For Sore Joints
& Achy Muscles

42% **Ultra Aloe®**



Temporary, effective relief from...

- Sore joints
- Minor muscular aches and pains
- Arthritis & Backache



Pain Relieving Cream

Net Wt 4 oz (112 g)

MIRACLE RUB

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66391-1603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 106 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 106 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
IMIDUREA (UNII: M629807ATL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MANGO (UNII: I629I3NR86)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66391-1603-4	112 g in 1 TUBE; Type 0: Not a Combination Product	10/31/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/31/2016	

Labeler - Winning Solutions (962718300)**Registrant** - Winning Solutions (962718300)