

MIRACLE HEEL REPAIR - allantoin , dimethicone 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 : Allantoin 1.0 % , Dimethicone 1.0 %

Purpose : Skin Protectant

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 2 years and older apply as needed

under 2 years ask a doctor.

wash and dry skin apply liberatly over attached area and massage until absorbed .

Uses: Temporary protects and helps relieve chapped or cracked skin

aloe barabardensis leaf Juice , water , PEG 8, stearic acid , PEG-100 stearte , glyceryl stearate , cetearyl alcohol, polysorbate 60 , propylene glycol, mineral oil ,hydrogenated polyisobutene,cetyl alcohol , butyrospermum parkii (shea butter) , theobroma cacao (cocoa) seed butter , triethanolamine, mangifera indica (mango) seed butter, salicylic acid ,chondrus crispis (carageenan) , arthemis nobilis flower extract, fragrance, methylparaben, propylparaben, tetrasodium edta , bht, diazolidinyl urea

Winning Solutions Inc. - 4 oz. Ontel Miracle Heel Repair
 ART2849 2" x 4-1/4" Sleeve Color:
 Yellow 109c, Blue 2935c

11/23/05
 White

293

open end

Actual sleeve length 4-1/4"

shoulder

Miracle of Aloe
Miracle Heel Repair Cream

FAST ACTING RELIEF FOR:
 • Severe Cracks • Calluses
 • Roughness • Dryness

60% Ultra Aloe

- Repairs dry, cracked, damaged heels
- Soothes & softens skin
- Moisturizes, conditions and protects skin

Skin Protectant
 Net Wt 4 oz (112 g)



This product contains 60% pure Aloe Vera gel (*Ultra Aloe*) by volume (aloe barbadensis leaf juice) as certified by the International Aloe Science Council.

Drug Facts	
Active ingredient	Purpose
Allantoin 1.0%	Skin Protectant
Dimethicone 1.0%	Skin Protectant
Uses temporarily protects and helps relieve chapped or cracked skin	
Warnings For external use only.	
When using this product: <input type="checkbox"/> do not get into eyes	
Stop use and ask a doctor if: <input type="checkbox"/> condition worsens <input type="checkbox"/> symptoms last more than 7 days or clear up and occur again within a few days	
Do not use on: <input type="checkbox"/> deep or puncture wounds <input type="checkbox"/> animal bites <input type="checkbox"/> serious burns	
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 2 years and older: apply as needed <input type="checkbox"/> under 2 years: ask a doctor <input type="checkbox"/> wash and dry skin, apply liberally over affected area and massage until absorbed	
Inactive ingredients aloe barbadensis leaf juice, water, PEG-8, stearic acid, PEG-100 stearate, glyceryl stearate, cetearyl alcohol, polysorbate 60, propylene glycol, mineral oil, hydrogenated polyisobutene, cetyl alcohol, butyrospermium parkii (shea butter), theobroma cacao (cocoa) seed butter, sthirocolomine, mangifera indica (mango) seed butter, salicylic acid, chondrus crispus (carrageenan), arctostaphylos flower extract, fragrance, methylparaben, propylparaben, tetrasodium edta, bit, diszolidiyl urea	



Distributed by ONTEL PRODUCTS CORP.
 Fairfield, NJ 07004

© 2004, Jess Clarke & Sons, Inc. Miracle of Aloe®, Miracle Heel Repair™ and UltraAloe™ are registered trademarks of Jess Clarke & Sons, Inc. © Ontel Products Corp. All rights reserved. 1104

1/4"

Print height 3-7/8"

1/8" Min.

Melby Giffen
 12/14/2005

Proof Approval

Signature: *Melby Giffen*

Date: *11/29/05*

PROOF IS NOT INTENDED FOR A COLOR MATCH
 This print is provided as a check for copy and position

MIRACLE HEEL REPAIR

allantoin, dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66391-0604
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	1.12 g in 112 g
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1.12 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Water (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
Stearic Acid (UNII: 4ELV7Z65AP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
Mineral Oil (UNII: T5L8T28FGP)	
Cetyl Alcohol (UNII: 936JST6JCN)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TROLAMINE (UNII: 9O3K93S3TK)	
MANGO (UNII: I629B3NR86)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
CHONDRUS (UNII: XR12Z4HLEA)	
CHAMOMILE (UNII: FGL3685T2X)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
EDETATE SODIUM (UNII: MP1J8420LU)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66391-0604-0	112 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	03/16/2009	

Labeler - Winning Solutions (962718300)

Registrant - Beautymanufacturing Solutions Corporation (783200723)

Revised: 3/2011

Winning Solutions