NANOCARE- dimethicone lotion Dermazone Solutions, Inc.

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.

nanocare for skin

Drug Facts

Active ingredients

Dimethicone 1.0%

Purpose

Skin protectant

Uses

• helps prevent and relieve chafed or cracked skin

Warnings

For external use only.

When using this product keep out of eyes.

Do not use on

- deep wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens
- symptoms lasts more than seven days or clear up and occur again within a few days

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply to dry areas as needed
- children under 6 months: Ask a doctor

Inactive ingredients

USP water, mineral oil, petrolatum, alcohol, glyceryl stearate, PEG-100 stearate, paraffin, lecithin, polysorbate 60, DEA-cetyl phosphate, carbomer, imidazolidinyl urea, methylparaben, propylparaben, triethanolamine, essential oils

Manufactured by:

Dermazone Solutions, Inc.

2440 30th Avenue North St. Petersburg, FL 33713 USA Distributed by: Universal Sales & Marketing, Inc.

PRINCIPAL DISPLAY PANEL - 236 mL Bottle Label

nanocare

for skin

Penetrating Moisturizing Body Lotion

with sealing barrier

Clinical Skin Care with Lyphazome® Technology

8.0 FL OZ (236 mL)



Penetrating Moisturizing Body Lotion

with sealing barrier

Clinical Skin Care
with Lyphazome® Technology

8.0 FL OZ (236 mL)

This lotion delivers continuous hydrating action with Lyphazoome® technology througout the day.

Drug Facts

Active ingredients

Dimethicone 1.0%

Purpose

Skin protectant

Uses

· helps prevent and relieve chafed or cracked skin

Warnings

For external use only.

When using this product keep out of eyes.

Do not use on

- deep wounds
- · animal bites
- serious burns

Stop use and ask a doctor if

- · condition worsens
- symptoms lasts more than seven days or clear up and occur again within a few days

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- · apply to dry areas as needed
- · children under 6 months: Ask a doctor

Inactive ingredients

USP water, mineral oil, petrolatum, alcohol, glyceryl stearate, PEG-100 stearate, paraffin, lecithin, polysorbate 60, DEA-cetyl phosphate, carbomer, imidazolidinyl urea, methylparaben, propylparaben, triethanolamine, essential oils

Manufactured by:

Dermazone Solutions, Inc.
2440 30th Avenue North St. Petersburg, FL 33713 USA
Distributed by: Universal Sales & Marketing, Inc.

1-855-USA-1212 U.S. Patent App. Nos. 60/755,171 | 11/644,281 | 12/772,838 | 06851496.7 EU Patent App No. PCT/US06/48770 Made in the USA

PR PB104_00

dimethicone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58466-013	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	10 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
mineral oil (UNII: T5L8T28FGP)		
petrolatum (UNII: 4T6H12BN9U)		
alcohol (UNII: 3K9958V90M)		
glyceryl monostearate (UNII: 230 O U9 XXE4)		
PEG-100 stearate (UNII: YD01N1999R)		
paraffin (UNII: 1900E3H2ZE)		
polysorbate 60 (UNII: CAL22UVI4M)		
diethanolamine cetyl phosphate (UNII: 4UG0316V9S)		
imidurea (UNII: M629807ATL)		
methylparaben (UNII: A2I8C7HI9T)		
propylparaben (UNII: Z8IX2SC1OH)		
trolamine (UNII: 9O3K93S3TK)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58466-013-13	88 mL in 1 BOTTLE		
2	NDC:58466-013-18	236 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part332	11/0 1/20 12		

Labeler - Dermazone Solutions, Inc. (136116865)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dermazone Solutions, Inc.		136116865	MANUFACTURE(58466-013)	

Revised: 10/2012 Dermazone Solutions, Inc.