

NANOCARE- dimethicone cream
Deramzone 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
Penetrating Moisturizing Cream

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, cetyl alcohol, lecithin, essential oils, imidazolidinyl urea, methylparaben, propylparaben, triethanolamine

Manufactured by:

Dermazone Solutions, Inc.

2440 30th Avenue North St. Petersburg, FL 33713 USA

Distributed by: Universal Sales & Marketing, Inc.

PRINCIPAL DISPLAY PANEL - 118 mL Jar Label

nanocare
for skin

Penetrating
Moisturizing Cream
with sealing barrier
4.0 FL OZ (118 mL)



Penetrating
Moisturizing Cream
with sealing barrier

4.0 FL OZ (118 mL)

This cream delivers continuous hydrating action with Lyphazome® technology throughout the day.

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
Active ingredients Dimethicone 1.0%	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.	Inactive ingredients USP water, mineral oil, petrolatum, alcohol, glyceryl stearate, PEG-100 stearate, paraffin, cetyl alcohol, lecithin, essential oils, imidazolidinyl urea, methylparaben, propylparaben, triethanolamine
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Uses • helps prevent and relieve chafed or cracked skin	Directions • apply to dry areas as needed • children under 6 months: Ask a doctor	Manufactured by: Demazone 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
Warnings For external use only. When using this product keep out of eyes.		PR_PJ48_00

NANOCARE

dimethicone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58466-024
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: 230OU9XXE4)	
PEG-100 stearate (UNII: YD01N1999R)	
paraffin (UNII: I9O0E3H2ZE)	
cetyl alcohol (UNII: 936JST6JCN)	
imidurea (UNII: M629807ATL)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58466-024-24	118 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part332	10/15/2012	

Labeler - Deramzone Solutions, Inc. (136116865)

Establishment

Name	Address	ID/FEI	Business Operations
Deramzone Solutions, Inc.		136116865	MANUFACTURE(58466-024)

Revised: 10/2012

Deramzone Solutions, Inc.