DYNASHIELD WITH DIMETHICONE- zinc oxide cream Dynarex Corporation

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.

1199 Dynashield with Dimethicone NDC 67777-408-03

Active Ingredients

Zinc Oxide 2%

Dimethicone 1.8%

Purpose

- Diaper rash
- Skin Protectant

Uses

- Use as a general skin protectant
- Helps treat chafed skin associated with diaper rash
- Dries the oozing and weeping of poison ivy, oak, and sumac

Warnings

For External Use Only.

When using this product:

- Avoid contact with eyes
- Do not use over large areas of the body
- So not use if you are allergic to any of the ingredients

Stop use and ask a doctor if:

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

• For diaper rash: Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply cream liberally as often as

necessary with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

• For other uses: Apply as needed.

Other Information

- Store at room temperature between 15 0 30 0 C (59 0 86 0 F)
- Avoid excessive heat
- Tamper evident. Do not use if seal is damaged.

Inactive Ingredients

Aloe Vera Leaf, Alpha-Tocopherol (Vitamin E), Cetomacrogol 1000, Cetostearyl Alcohol, Cetyl Alcohol, Glycerin, Lanolin, Lavender Oil, Methylparaben, Mineral Oil, Propylparaben, Tartrazine, Trolamine, Vitamin A Acetate, Vitamin D3, Water, White Soft Paraffin

Questions and Comments?

1-888-396-2739, Monday - Friday 9AM-5PM EST

Label





DYNASHIELD®

WITH DIMETHICONE

· Vitamin A · Vitamin D · Vitamin E · Zinc Oxide · Aloe Vera



4 oz. (113 g)

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Reorder No. 1199

Manufactured for: Dynarex Corporation 10 Glenshaw Street • Orangeburg, NY 10962 USA • www.dynarex.com

Made in India R220413



DynaShield with Dimehticone

DYNASHIELD WITH DIMETHICONE

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-408
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	1.8 g in 100 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
VITAMIN A ACETATE (UNII: 3LE3D9D6OY)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LANOLIN (UNII: 7EV65EAW6H)	
CETETH-20 (UNII: 1835H2IHHX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67777-408- 02	24 in 1 CASE	10/01/2014		
1	NDC:67777-408- 03	114 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M016	10/01/2014		

Registrant - Dynarex Corporation (008124539)

Revised: 5/2023 Dynarex Corporation