

DYNASHIELD- 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.

1195, 1196

Active Ingredient

Zinc Oxide 1.8%

Purpose

Skin Protectant

Uses

- Helps treat chafed skin associated with diaper rash
- Temporarily protects minor • cuts • scrapes • burns
- Dries the oozing and weeping of poison ivy, oak, sumac

Warnings

For External Use Only

When using this product

- Do not get in eyes

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°-30°C (59°-86°F)
- Avoid excessive heat
- Tamper evident. Do not use if seal is damaged.

Inactive Ingredients

Glycerin, Cetostearyl Alcohol, Cetyl Alcohol, White Soft Paraffin, Mineral Oil, Lanolin, Cetomacrogol 1000, Aloe Vera Leaf, Methyl Paraben, Propyl Paraben, Perfume Lavander Oil, Alpha Tocopherol, Trolamine, Vitamin A Acetate, Cholecalciferol (Vitamin D3), FD&C Yellow No. 5 (Tartrazine), Water

1195 Label

UNPRINTED AREA FOR SEALING



DYNASHIELD®

SKIN PROTECTANT

- Aloe Soft • Vitamin Enriched
- Vitamin A • Vitamin D
- Vitamin E • Zinc Oxide
- Aloe Vera

**Enhanced
Formula**

4 oz. (113 g)

Drug Facts

Active Ingredient

Zinc Oxide 1.8%.....Skin Protectant

Purpose

Use(s)

- Helps treat chafed skin associated with diaper rash
- Temporarily protects minor cuts, scrapes, and burns
- Dries the oozing and weeping of poison ivy, oak, and sumac

Warnings

For external use only

When using this product ■ Avoid contact with eyes.

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

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- For other uses: Apply as needed.

Other Information

- Store at room temperature between 15°-30°C (59°-86°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

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

Made in India R211013

Reorder No. 1195



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Reorder No. 1196

Drug Facts	
Active Ingredient Zinc Oxide 1.8%	Purpose Skin Protectant
Use(s) <ul style="list-style-type: none"> Helps treat chafed skin associated with diaper rash Temporarily protects minor cuts, scrapes, and burns Dries the oozing and weeping of poison ivy, oak, and sumac 	
Warnings For external use only When using this product <ul style="list-style-type: none"> Avoid contact with eyes. Stop use and ask a doctor if <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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. 	
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Inactive Ingredients Aloe Vera Leaf, Alpha Tocopherol (Vitamin E), Calciummagnesium 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	

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Dynarex Corporation
10 Glenshaw Street
Orangeburg, NY 10962
USA • www.dynarex.com
Made in India RE11013

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit www.dynarex.com/symbols.php



Net Wt. 16 oz. (453.6 g)

DYNASHIELD

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-407
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
LANOLIN (UNII: 7EV65EAW6H)	
CETETH-20 (UNII: I835H2IHHX)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-407-	5 g in 1 PACKET; Type 0: Not a Combination	05/23/2010	

1	01	Product	05/23/2018	
2	NDC:67777-407-02	15 g in 1 PACKET; Type 0: Not a Combination Product	05/23/2018	
3	NDC:67777-407-10	24 in 1 CASE	10/01/2014	
3	NDC:67777-407-03	114 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:67777-407-11	12 in 1 CASE	10/01/2014	
4	NDC:67777-407-04	427.5 g in 1 JAR; 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	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 5/2023

Dynarex Corporation