

ZINC OXIDE - zinc oxide ointment

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.

Zinc Oxide Ointment

Active Ingredient	Purpose
Zinc Oxide (1.8% w/w)	Skin Protectant

Purpose:

- Helps treat and prevent diaper rash
- Temporarily protects
- minor cuts
- scrapes and
- burns
- dries the oozing and weeping of
- poison ivy
- poison oak
- poison 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 in a few days, consult a physician

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Dosage and Administration:

For skin protectant:

- Apply liberally as needed

For diaper Rash:

- change wet and soiled diapers promptly
- allow to dry
- apply ointment liberally with each diaper change

Other information:

- Store at room temperature

- avoid excessive heat
- contains color additives including FDC yellow # 5

Indications: For use as a general skin protectant and diaper rash.

Inactive ingredients:

Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-10, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Phenoxyethanol, Polyethylene Glycol 6000, Polysorbate 60, Propylparaben Sodium, Steareth-20, Trolamine, Vitamin A, Water

Principal Display Panel

Dynarex DynaShield Skin Protectant

zinc_oxide.jpg

144 Packets

NDC #67777-226-01

Drug Facts

Active Ingredient	Purpose
Zinc Oxide (1.8% w/w)	Skin Protectant

Uses: • Helps treat and prevent diaper rash. • Temporarily protects: • minor cuts • scrapes • burns • Dries the oozing and weeping of: • poison ivy • poison oak • poison sumac

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- Condition worsens • Symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away

Directions: • Apply liberally as needed • For diaper rash: • change wet and soiled diapers promptly • allow to dry • Apply ointment liberally with each diaper change

Other information: • Store at room temperature 15° - 30°C (59° - 86°F) • Avoid excessive heat • Contains color additives including FD&C Yellow No. 5 (Tartrazine).

Inactive ingredients Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-10, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Phenoxyethanol, Polyethylene Glycol 6000, Polysorbate 60, Propylparaben Sodium, Steareth-20, Trolamine, Vitamin A, Water

Manufactured for:
Dynarex Corporation
Orangeburg, NY 10962
www.dynarex.com

Made in India

Each Packet
Net Wt. 5g
Reorder No. 1193

144 Packets

Enhanced Formula

DynaShield™
Skin Protectant

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Made in India

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144 Packets

Enhanced Formula

DynaShield™
Skin Protectant

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

Each Packet
Net Wt. 5g
Reorder No. 1193

ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-226
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
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LANOLIN (UNII: 7EV65EAW6H)
CETETH-10 (UNII: LF9X1PN3XJ)
MINERAL OIL (UNII: T5L8T28FGP)
PARAFFIN (UNII: I9O0E3H2ZE)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CETYL ALCOHOL (UNII: 936JST6JCN)
STEARETH-20 (UNII: L0Q8IK9E08)
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)
POLYSORBATE 60 (UNII: CAL22UVI4M)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CHOLECALCIFEROL (UNII: 1C6V77QF41)
VITAMIN A (UNII: 81G40H8B0T)
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
PETROLATUM (UNII: 4T6H12BN9U)
TROLAMINE (UNII: 9O3K93S3TK)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-226-01	144 in 1 BOX		
1		5 g in 1 PACKET		
2	NDC:67777-226-02	36 in 1 BOX		
2		15 g in 1 PACKET		
3	NDC:67777-226-03	24 in 1 CASE		
3		114 g in 1 TUBE		
4	NDC:67777-226-04	427.5 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2011	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)