

**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.*

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**Zinc Oxide Ointment**

Section Text

Active Ingredient	Purpose
Zinc Oxide (200mg in each gram)	Skin Protectant

**Purpose:**

- Helps treat and prevent diaper rash.
- 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:**

- conditions worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician.
- over large areas of the body
- if you are allergic to any of these ingredients

**Do not use on:**

- deep or puncture wounds
- animal bites
- serious burns

**Keep out of reach of children**

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

**Directions:**

**For diaper rash:**

- change wet and soiled diapers promptly
- cleanse the diaper area and allow to dry

- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

**For poison ivy, poison oak, poison sumac:**

- apply liberally as often as needed

**Inactive Ingredients**

Cetostearyl alcohol, Cetomacrogol 1000, Light Liquid Paraffin, White Soft Paraffin

**Principal Display**

zinc.jpg

<b>Drug Facts</b> <b>Active Ingredient</b> Zinc Oxide 20% w/w ..... Skin Protectant <b>Purpose</b> Skin Protectant <b>Uses</b> • Helps treat and prevent diaper rash • Dries the oozing and weeping of: • Poison Ivy • Poison Oak • Poison Sumac <b>Warnings: FOR EXTERNAL USE ONLY.</b> <b>When using this product</b> • do not get into the eyes • do not use over large areas of the body. ▶		<b>Drug Facts (continued)</b> <b>Stop use and ask a doctor if</b> • the condition worsens • symptoms last more than 7 days or clear up and occur again in a few days • if you are allergic to any of these ingredients <b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b> ▼	
<b>Drug Facts (continued)</b> <b>Directions</b> • For diaper rash: • change wet and soiled diapers promptly • cleanse the diaper area and allow to dry • apply ointment liberally with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged • For Poison Ivy, Oak, and Sumac: • apply ointment liberally as often as needed ▶		<b>Drug Facts (continued)</b> <b>Other information</b> • Store at 59° - 86°F (15° - 30°C) • Avoid excessive heat. <b>Inactive Ingredients</b> Cetostearyl Alcohol, Cetomacrogol 1000, Light Liquid Paraffin, White Soft Paraffin	

Net Wt. 1 OZ (28.4g)  
Reorder No. 1190

**Zinc Oxide Ointment**  
Skin Protectant



Manufactured for:  
Dynarex Corporation  
Orangeburg, NY 10962  
www.dynarex.com  
Made in India  
NDC # 67777-222-03

MHDRUGSKD-214

**ZINC OXIDE**

zinc oxide ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-222
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67777-222-03	28.34 g in 1 TUBE; Type 0: Not a Combination Product	03/17/20 10	
2	NDC:67777-222-01	56.68 g in 1 TUBE; Type 0: Not a Combination Product	03/17/20 10	
3	NDC:67777-222-02	425.1 g in 1 JAR; Type 0: Not a Combination Product	03/17/20 10	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347	03/16/20 10	

**Labeler** - Dynarex Corporation (008124539)**Registrant** - Dynarex Corporation (008124539)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Galentic Pharma (India) Pvt. Ltd.		864201135	manufacture(67777-222)