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
Product Information

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

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)</td>
<td>ZINC OXIDE</td>
<td>200 mg in 1 g</td>
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Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
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<tbody>
<tr>
<td>CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)</td>
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<tr>
<td>CETETH-20 (UNII: B35H21HHX)</td>
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<tr>
<td>LIGHT MINERAL OIL (UNII: N6K5787QVP)</td>
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<td>PETROLATUM (UNII: 4T6HI2BN9U)</td>
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Packaging

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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>28.34 g in 1 TUBE; Type 0: Not a Combination Product</td>
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<td>425.1 g in 1 JAR; Type 0: Not a Combination Product</td>
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Marketing Information

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<td>OTC monograph final</td>
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Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

<table>
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<tr>
<th>Name</th>
<th>Address</th>
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<td>Galentic Pharma (India) Pvt. Ltd.</td>
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<td>864201135</td>
<td>manufacture(67777-222)</td>
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Revised: 4/2017