MENTHOL AND ZINC OXIDE- menthol and 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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1271 Calasoothe Ointment NDC 67777-234-01
1275 Calasoothe Ointment NDC 67777-234-03

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menthol 0.44% v/v</td>
<td>External Analgesic</td>
</tr>
<tr>
<td></td>
<td>First Aid Antiseptic</td>
</tr>
<tr>
<td></td>
<td>Antipuritic</td>
</tr>
<tr>
<td>Zinc Oxide 20.625% v/v</td>
<td>Skin Protectant</td>
</tr>
<tr>
<td></td>
<td>Moisture Barrier</td>
</tr>
</tbody>
</table>

Purpose:

A moisture barrier that prevents and helps heal skin irritations from:
- urine
- diarrhea
- perspiration
- fistula drainage
- feeding tube site leakage
- wound drainage (peri-wound skin)
- minor burns
- cuts
- scrapes
- itching

Warnings:

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

Indications & Usage

- Not for deep or puncture wounds.
- Avoid contact with eyes.
- If condition worsens or does not improve within 7 days, consult a doctor

Dosage & Administration:

- Clean skin with mild skin cleanser
- Pat dry or allow to air dry
- Apply a thin layer of Calasoothe to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection

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.

Inactive Ingredients
Inactive Ingredients: Calamine, Glycerine, Phenol, Lanolin, Heavy Liquid Paraffin, Sodium Bicarbonate, Thymol, White Soft Paraffin

1271 Label
Promotes Healing

Protects, Soothes and

CalaSoothe

Drug Facts

Active Ingredients Purpose
Menthol 0.44% ............. External Analgesic
Zinc Oxide 20.625% ........ Skin Protectant

Uses
■ A moisture barrier that prevents & helps heal skin irritations from:
  • urine • diarrhea • perspiration
  • fistula drainage
  • feeding tube site leakage
  • wound drainage (peri-wound skin)
  • minor burns • cuts • scrapes • itching

Warnings
For External Use Only.
■ Not for deep or puncture wounds
■ Avoid contact with eyes
■ Stop use and ask a doctor if 
  ■ condition worsens
  ■ symptoms last more than 7 days
  ■ 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 right away.

Drug Facts (continued)

Directions
■ Cleanse skin with mild skin cleanser
■ Pat dry or allow to air dry
■ Apply a thin layer of Calasoothe to reddened or irritated skin 2-4 times daily,
or after each incontinent episode or diaper change to promote comfort and long lasting protection

Other information
■ Store at room temperature 20° - 25°C
  (68° - 77°F)

Tamper Evident
Do not use if packet is torn or cut.

Inactive Ingredients
Calamine, Glycerin, Lanolin, Mineral Oil,
Phenol, Sodium Bicarbonate, Thymol,
White Soft Paraffin

Questions?
1-888-DYNAREX Monday-Friday,
9AM-5PM EST.

Keep this box for complete Drug Facts.
# MENTHOL AND ZINC OXIDE

**menthol and zinc oxide ointment**

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:67777-234</td>
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<tr>
<td>Route of Administration</td>
<td>TOPICAL</td>
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## Drug Facts

### Active Ingredients

- Menthol 0.44%         ... External Analgesic
- Zinc Oxide 20.625%    ... Skin Protectant

### Uses

- A moisture barrier that prevents & helps heal skin irritations from: urine, diarrhea, perspiration, fistula drainage, feeding tube site leakage, wound drainage (peri-wound skin), minor burns, cuts, scrapes, itching.

### Warnings

**For external use only.**
- Not for deep or puncture wounds
- Avoid contact with eyes
- Stop use and ask a doctor if condition worsens, symptoms last more than 7 days, or occur again within a few days
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

- Cleanse skin with mild skin cleanser.
- Pat dry or allow to air dry.
- Apply a thin layer of Calasoothe to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection.

### Other Information

- Store at room temperature 20°-25°C (68°-77°F).

### Inactive Ingredients

- Calamine, Glycerin, Lanolin, Mineral Oil, Phenol, Sodium Bicarbonate, Thymol, White Soft Paraffin.

### Questions?

1-888-DYNAREX Monday – Friday, 9AM – 5PM EST.
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)</td>
<td>MENTHOL</td>
<td>0.44 g in 100 g</td>
</tr>
<tr>
<td>ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)</td>
<td>ZINC OXIDE</td>
<td>21 g in 100 g</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<tr>
<td>PHENOL (UNII: 339NCG44TV)</td>
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<td>LANOLIN (UNII: 7EV65EAW6H)</td>
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<tr>
<td>MINERAL OIL (UNII: T5L8T28FGP)</td>
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<tr>
<td>SODIUM BICARBONATE (UNII: 8MDF5V39QO)</td>
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<td>THYMOL (UNII: 3J50XA376E)</td>
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### Packaging

<table>
<thead>
<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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<tr>
<td>1</td>
<td>NDC:67777-234-01</td>
<td>2 in 1 CASE</td>
<td>05/11/2010</td>
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<tr>
<td>1</td>
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<td>144 in 1 BOX</td>
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<tr>
<td>1</td>
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<td>2</td>
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<td>113 g in 1 TUBE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
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<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph final</td>
<td>part347</td>
<td>05/11/2010</td>
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### Labeler
- Dynarex Corporation (008124539)

### Registrant
- Dynarex Corporation (008124539)

Revised: 9/2019