

**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**

***Active Ingredient***

Menthol 0.44%

Zinc Oxide 20.625%

***Purpose***

External Analgesic

Skin Protectant

***Uses***

- 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***

For external use only

***When using this product***

- Avoid contact with eyes

***Do not use section***

- On deep or puncture wounds

***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***

- 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 15°-30° C (59°-86° F)
- Tamper evident. Do not use if packet is torn or cut. Do not use if seal is damaged.

### ***Inactive Ingredients***

Calamine, Glycerine, Lanolin, Mineral Oil, Phenol, Sodium Bicarbonate, Thymol, White Soft Paraffin

### ***Questions?***

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

### ***Label***



# CALASOOOTHE<sup>®</sup>

*Protects, Soothes, and Promotes Healing*

**Net Wt. 4 oz.  
(113 g)**

Calasoothe 4 oz. tube

**Label**

## Drug Facts

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Zinc Oxide 20.625% .....	Skin Protectant

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  - Fistula drainage ■ Feeding tube site leakage
  - Wound drainage (peri-wound skin)
  - Minor burns ■ Cuts ■ Scrapes ■ Itching

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- Avoid contact with eyes

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### Questions?

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**Manufactured for:**  
 Dynarex Corporation  
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 Orangeburg, NY 10962  
 USA • [www.dynarex.com](http://www.dynarex.com)  
 Made in India R220513

**Reorder No. 1275**







1271 Calasoothe

## MENTHOL AND ZINC OXIDE

menthol and zinc oxide ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-234
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOL</b> (UNII: 339NCG44TV)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

**SODIUM BICARBONATE** (UNII: 8MDF5V39QO)

**THYMOL** (UNII: 3J50XA376E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-234-01	2 in 1 CASE	05/11/2010	
1	NDC:67777-234-02	144 in 1 BOX		
1		3.5 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67777-234-03	24 in 1 CASE	05/11/2010	
2	NDC:67777-234-04	113 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/11/2010	

**Labeler** - Dynarex Corporation (008124539)

**Registrant** - Dynarex Corporation (008124539)

Revised: 12/2022

Dynarex Corporation