

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.

Calasoothe Ointment

Active Ingredient

Menthol 0.44% v/v

Zinc Oxide 20.625% v/v

Purpose

External Analgesic

First Aid Antiseptic

Antipuritic

Skin Protectant

Moisture Barrier

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

Principal Display Panel

Principal Display Panel - Calasoothe_Ointment

Calasoothe.jpg

NDC# 67777-409-03



CalaSoothe[®]

Protects, Soothes and Promotes Healing

Reorder No.1275
Net Wt. 4 OZ (113g)



GO/DRUGS/910/L

Drug Facts	
Active Ingredient	Purpose
Menthol 0.44%	External Analgesic, First Aid
.....	Antiseptic, Antipruritic
Zinc Oxide 20.625%	Skin Protectant
.....	Moisture Barrier
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 • If condition worsens or does not improve within 7 days, consult a doctor.	
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)	
Tamper Evident Do not use if tube is broken or damaged.	
Inactive ingredients Calamine, Glycerine, Heavy Liquid Paraffin, Phenol, Lanolin, Sodium Bicarbonate, Thymol, White Soft Paraffin.	

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

Made in India

MENTHOL AND ZINC OXIDE

menthol and zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-409
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.44 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOL (UNII: 339NCG44TV)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-409-01	3.5 g in 1 POUCH		
2	NDC:67777-409-02	71 g in 1 JAR		
3	NDC:67777-409-03	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/11/2014	

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