

MENTHOL AND ZINC OXIDE- menthol and zinc oxide ointment
Marlex Pharmaceuticals, Inc.

Menthol and Zinc Oxide Ointment - anorectal Ointment

Active Ingredients

Menthol 0.44%

Zinc Oxide 20.625%

Purpose

External Analgesic

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 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 right away.

Directions

- Cleans with mild skin cleanser
- Pat dry or allow to air dry
- Apply a thin layer of ointment 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°F-77°F)

Inactive Ingredients

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

Package label

Menthol and Zinc Oxide Ointment

NDC 10135-0701-04



Menthol and Zinc Oxide Ointment

Anorectal Ointment • temporarily protects irritated areas

• temporary relief of pain or burning and skin irritations

FOR EXTERNAL USE ONLY

Net Wt. 4 oz. (113 g)

*Compare to the Active ingredients in Calmoseptine® Ointment

60/DRUGS/910/L

Made in India

Drug Facts	Purpose
Active Ingredients	
Menthol 0.44%	External Analgesic
Zinc Oxide 20.625%	Skin Protectant
Uses	
<ul style="list-style-type: none"> ■ 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	
<p>For external use only</p> <ul style="list-style-type: none"> ■ Not for deep or puncture wounds ■ Avoid contact with eyes <p>Stop use and ask doctor if ■ condition worsens</p> <ul style="list-style-type: none"> ■ symptoms last more than 7 days or clear up and occur again within a few days <p>Keep out of reach of children.</p> <p>If swallowed, get medical help or contact a Poison Control Center right away. ▶</p>	

UNPRINT AREA FOR SEALING

Batch & Exp. on crimp

9

**This product is not manufactured or distributed by Calmoseptine Inc., owner of the registered trademark Calmoseptine® Ointment.

Drug Facts (continued)
Directions
<ul style="list-style-type: none"> ■ Cleanse with mild skin cleanser ■ Pat dry or allow to air dry ■ Apply a thin layer of ointment 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
<ul style="list-style-type: none"> ■ Store at room temperature 20°-25°C (68°F-77°F)
Inactive Ingredients
Calamine, Glycerine, Lanolin, Mineral Oil, Phenol, Sodium Bicarbonate, Thymol, White Soft Paraffin, Isopropyl Alcohol, Hard Paraffin

Manufactured for & Distributed by:
 Marlex Pharmaceuticals, Inc.
 New Castle, DE 19720
 Rev.1 05/22 BP



10135 70104

MENTHOL AND ZINC OXIDE

menthol and zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.625 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
LANOLIN (UNII: 7EV65EAW6H)	
THYMOL (UNII: 3J50XA376E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENOL (UNII: 339NCG44TV)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-701-04	113 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	05/01/2021	

Labeler - Marlex Pharmaceuticals, Inc. (782540215)