

CALMOSEPTINE- anorectal ointment ointment

Calmoseptine Inc.

Calmoseptine Ointment

Active Ingredients

Lanolin 15.7%

Menthol 0.44%

Petrolatum 24%

Zinc Oxide 20.6%

Purpose

Active Ingredients	Purpose
Lanolin 15.7%.....	Anorectal Protectant
Menthol 0.44%.....	Anorectal Analgesic
Petrolatum 24%.....	Anorectal Protectant
Zinc Oxide 20.6%.....	Anorectal Protectant, Astringent

Uses

- Temporarily protects irritated areas.
- For the temporary relief of:
 - local itching and discomfort in the perianal area
 - pain or burning
 - skin irritations

Warnings

For external use only

When using this product

- * Certain persons can develop allergic reactions to ingredients in this product.
- * Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- * Do not exceed the recommended daily dosage unless directed by a doctor.
- * Avoid contact with eyes.

Stop use and ask doctor if

- condition worsens or does not improve within 7 days
- bleeding occurs
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

Keep out of reach of children.

In case of accidental ingestion contact a physician or Poison Control Center immediately.

Directions

Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.

Gently dry by patting or blotting with toilet tissue or a soft cloth or air dry before application of this product.

Apply externally to the affected area up to 6 times daily or after each bowel movement. Children under 12 years of age: consult a doctor.

Inactive Ingredients:

calamine, chlorothymol, glycerin, phenol,

sodium bicarbonate, and thymol in a suitable ointment base

Calmoseptine Ointment



The Original

NDC 0799-0001-04

Net wt. 4oz (113g)

Calmoseptine[®] Ointment

Anorectal Ointment • temporarily protects irritated areas
• temporary relief of pain or burning and skin irritations

MADE IN USA Manufactured for Calmoseptine Inc., Huntington Beach, CA 92647
1-800-800-3405 www.calmoseptine.com

Drug Facts		Drug Facts (continued)	
Active ingredients	Purpose	Stop use and ask a doctor if	
Lanolin 15.7%.....Anorectal Protectant	Menthol 0.44%.....Anorectal Analgesic	• condition worsens or does not improve within 7 days • bleeding occurs • symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.	
Petrolatum 24%.....Anorectal Protectant	Zinc Oxide 20.6%...Anorectal Protectant, Astringent	Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center immediately.	
Uses • Temporarily protects irritated areas. • For the temporary relief of: • local itching and discomfort in the perianal area • pain or burning • skin irritations		Directions Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth or air dry before application of this product. • Apply externally to the affected area up to 6 times daily or after each bowel movement. • Children under 12 years of age: consult a doctor.	
Warnings For external use only		Other Information • Store between: 15-30°C (59-86°F)	
When using this product • Certain persons can develop allergic reactions to ingredients in this product. • Do not put this product into the rectum by using fingers or any mechanical device or applicator. • Do not exceed the recommended daily dosage unless directed by a doctor. • Avoid contact with eyes.		Inactive ingredients calamine, chlorothymol, glycerin, phenol, sodium bicarbonate, and thymol in a suitable ointment base	



CALMOSEPTINE

anorectal ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0799-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	15.7 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	24 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHLOROTHYMOL (UNII: LJ25TI0CVT)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOL (UNII: 339NCG44TV)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0799-0001-02	71 g in 1 TUBE; Type 0: Not a Combination Product	01/04/1999	
2	NDC:0799-0001-03	71 g in 1 JAR; Type 0: Not a Combination Product	08/01/1950	
3	NDC:0799-0001-04	113 g in 1 TUBE; Type 0: Not a Combination Product	08/01/1988	
4	NDC:0799-0001-05	3.5 g in 1 PACKET; Type 0: Not a Combination Product	06/01/2001	
5	NDC:0799-0001-06	20 g in 1 TUBE; Type 0: Not a Combination Product	07/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	08/01/1950	

Labeler - Calmoseptine Inc. (783409394)

Establishment

Name	Address	ID/FEI	Business Operations
Calmo Manufacturing Inc.		015850149	manufacture(0799-0001) , pack(0799-0001) , label(0799-0001)

Revised: 1/2025

Calmoseptine Inc.