

CALMOSEPTINE- anorectal ointment ointment

Calmoseptine Inc.

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.

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		• 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.
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		Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center immediately.
Warnings For external use only		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.
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.		Other Information • Store between: 15-30°C (59-86°F)
		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	
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 final		part346	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)	