

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

<p>Drug Facts</p> <p>Active ingredients Purpose</p> <p>Lanolin 15.7%.....Anorectal Protectant Menthol 0.44%.....Anorectal Analgesic Petrolatum 24%.....Anorectal Protectant Zinc Oxide 20.6%...Anorectal Protectant, Astringent</p>	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <p>• 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.</p> <p>Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center immediately.</p>
<p>Uses • Temporarily protects irritated areas.</p> <p>• For the temporary relief of: • local itching and discomfort in the perianal area • pain or burning • skin irritations</p>	<p>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.</p> <p>• Children under 12 years of age: consult a doctor.</p>
<p>Warnings For external use only</p> <p>When using this product</p> <p>• 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.</p>	<p>Other Information • Store between: 15-30°C (59-86°F)</p> <p>Inactive ingredients calamine, chlorothymol, glycerin, phenol, sodium bicarbonate, and thymol in a suitable ointment base</p>



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)