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.

Calmos eptine 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

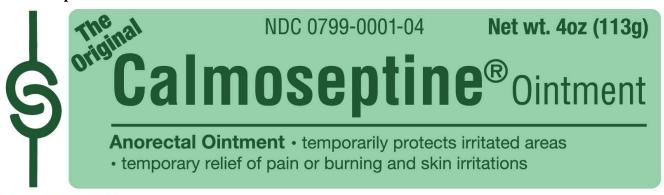
Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth or air dry before application of this product.

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



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

Drug Facts

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Menthol 0.44%.....Anorectal Analgesic
Petrolatum 24%.....Anorectal Protectant
Zinc Oxide 20.6%...Anorectal Protectant, Astringent

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Drug Facts (continued)

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Other Information • Store between: 15-30°C (59-86°F)

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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: 4T6 H12BN9 U) (PETROLATUM - UNII:4T6 H12BN9 U) | 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 O XIDE RED (UNII: 1K09F3G675) | | |
| CHLOROTHYMOL (UNII: LJ25TI0CVT) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| PHENOL (UNII: 339 NCG44TV) | | |
| SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO) | | |
| THYMOL (UNII: 3J50 XA376E) | | |

| P | 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. | | 0 158 50 149 | manufacture(0799-0001), pack(0799-0001), label(0799-0001) |

Revised: 1/2019 Calmoseptine Inc.