

## **RUGBY BARRIER CREAM- barrier cream cream**

### **Rugby Laboratories**

*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.*

-----

### **Drug Facts**

#### **Active ingredient**

Menthol 0.45%

Zinc Oxide 20%

#### **Purpose**

External Analgesic

Astringent

#### **Uses**

Multipurpose moisture barrier that aids in protecting irritated skin conditions in the perineum, buttocks, lower abdomen and inner thigh due to moisture, occlusion, chafing or continued contact with urine or feces.

Helps relieve the local itching, discomfort, pain, burning and irritation associated with anorectal disorders and hemorrhoids. May provide a cooling sensation.

#### **Warnings**

**For external use only**

**Stop use and consult a doctor**

**•in case of bleeding**

**•if conditions worsen or do not improve within 7 days**

**<Do not exceed recommended daily dosage unless directed by a doctor. Do not put product into rectum by using fingers or any mechanical device or applicator** Allergy Alert: Certain persons can develop allergic reactions to this product. If the symptoms develop or increase, discontinue use and consult a doctor. >

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

#### **Other information**

Store at controlled room temperature 20° - 25°C (68° - 77°F)

## Inactive ingredients

Calamine, Codliver Oil, Disodium EDTA, Lanolin, Methylparaben, Microcrystalline Wax, Mineral Oil, Petrolatum, Propylparaben, Sodium Borate, Sorbitan Sequioleate, Talc, Water (Purified)

## Principal Display Panel - Tube Label



Compare to the active ingredients  
in Calmoseptine® Ointment\*  
NDC 0536-1204-73

# Menthol Zinc Ointment

Anorectal Cream • Zinc Oxide 20% • Menthol 0.45%

NET WT. 113 g (4 oz.)

**Active Ingredients**  
Menthol 0.45% ..... External Analgesic  
Zinc Oxide 20% ..... Astringent

**Purpose**  
External Analgesic  
Astringent

**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 before application of this product.  
• Children under 12 years of age: consult a doctor.  
• Apply externally to the affected area up to 6 times daily.

**Other information** Store at controlled room temperature 20°-25°C (68°-77°F)

**Inactive ingredients** Calamine, Cod Liver Oil, Disodium EDTA, Lanolin, Methylparaben, Microcrystalline Wax, Mineral Oil, Petrolatum, Propylparaben, Sodium Borate, Sorbitan Sesquileate, Talc, Water (Purified)

**Questions or comments?** 1-800-645-2158

**KEEP CARTON FOR COMPLETE DRUG FACTS.**  
Dist. By Rugby Laboratories  
17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA  
Re-Order No. : 370661 Rev. 10/18 R-101  
\* This product is not manufactured or distributed by Calmoseptine, Inc., the distributor of Calmoseptine® Ointment.

2503901

NDC 0536-1204-73

Rugby

Menthol Zinc Ointment

Anorectal Cream

0.45% Menthol -External Analgesic

20% Zinc Oxide -Astringent

• Protect and soothes irritated or chafed skin associated with incontinence

• Temporary relief of pain & itching

NET WT. 4 oz. (113g)



Compare to the active ingredients  
in Calmoseptine® Ointment\*

NDC 0536-1204-73

# Menthol Zinc Ointment

Anorectal Cream • Zinc Oxide 20% • Menthol 0.45%

NET WT. 113 g (4 oz.)

#### Active Ingredients

Menthol 0.45% ..... External Analgesic  
Zinc Oxide 20% ..... Astringent

**Uses:** A multi-purpose moisture barrier that aids in protecting irritated skin conditions in the perineum, buttocks, lower abdomen and inner thighs due to moisture, occlusion, chafing or continued contact with urine or feces. Helps relieve the local itching, discomfort, pain, burning and irritation associated with anorectal disorders and hemorrhoids. May provide a cooling sensation.

**Warnings:** For external use only. Stop use and consult a doctor • in case of bleeding • if condition worsens or does not improve within 7 days. Do not exceed recommended daily dosage unless directed by a doctor. Do not put product into rectum by using fingers or any mechanical device or applicator. Allergy Alert: Certain persons can develop allergic reactions to this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Purpose

External Analgesic  
Astringent

**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 before application of this product.

• Children under 12 years of age: consult a doctor.

• Apply externally to the affected area up to 6 times daily.

**Other information:** Store at controlled room temperature 20°-25°C (68°-77°F)

**Inactive ingredients:** Calamine, Cod Liver Oil, Disodium EDTA, Lanolin, Methylparaben, Microcrystalline Wax, Mineral Oil, Petrolatum, Propylparaben, Sodium Borate, Sorbitan Sesquileate, Taic, Water (Purified)

**Questions or comments?** 1-800-645-2158

#### KEEP CARTON FOR COMPLETE DRUG FACTS.

Dist. By Rugby Laboratories

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA

Re-Order No. : 370661 Rev. 10/18 R-101

\* This product is not manufactured or distributed by Calmoseptine, Inc., the distributor of Calmoseptine® Ointment.

2503901



Compare to the active ingredients  
in Calmoseptine® Ointment\*

NDC 0536-1204-73

# Menthol Zinc Ointment

Anorectal Cream • Zinc Oxide 20% • Menthol 0.45%

NET WT. 113 g (4 oz.)

#### Active Ingredients

Menthol 0.45% ..... External Analgesic  
Zinc Oxide 20% ..... Astringent

**Uses:** A multi-purpose moisture barrier that aids in protecting irritated skin conditions in the perineum, buttocks, lower abdomen and inner thighs due to moisture, occlusion, chafing or continued contact with urine or feces. Helps relieve the local itching, discomfort, pain, burning and irritation associated with anorectal disorders and hemorrhoids. May provide a cooling sensation.

**Warnings:** For external use only. Stop use and consult a doctor • in case of bleeding • if condition worsens or does not improve within 7 days. Do not exceed recommended daily dosage unless directed by a doctor. Do not put product into rectum by using fingers or any mechanical device or applicator. Allergy Alert: Certain persons can develop allergic reactions to this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### Purpose

External Analgesic  
Astringent

**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 before application of this product.

• Children under 12 years of age: consult a doctor.

• Apply externally to the affected area up to 6 times daily.

**Other information:** Store at controlled room temperature 20°-25°C (68°-77°F)

**Inactive ingredients:** Calamine, Cod Liver Oil, Disodium EDTA, Lanolin, Methylparaben, Microcrystalline Wax, Mineral Oil, Petrolatum, Propylparaben, Sodium Borate, Sorbitan Sesquileate, Taic, Water (Purified)  
**Questions or comments?** 1-800-645-2158

#### KEEP CARTON FOR COMPLETE DRUG FACTS.

Dist. By Rugby Laboratories

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA

Re-Order No. : 370661 Rev. 10/18 R-101

\* This product is not manufactured or distributed by Calmoseptine, Inc., the distributor of Calmoseptine® Ointment.

2503901

Principal Display Panel - Carton



NDC 0536-1204-73

Rugby

Menthol Zinc Ointment

Anorectal Cream

0.45% Menthol

20% Zinc Oxide

Net Wt. 4 oz 113 g



## RUGBY BARRIER CREAM

barrier cream cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1204 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 200 mg in 1 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)       | MENTHOL           | 4.5 mg in 1 g |

### Inactive Ingredients

| Ingredient Name                                      | Strength |
|--|----------|
| FERRIC OXIDE RED (UNII: 1K09F3G675)                  |          |
| COD LIVER OIL (UNII: BBL281NWFQ)                     |          |
| DISODIUM ETHYLENEDIAMINEDIACETATE (UNII: EQL53S5L0F) |          |
| LANOLIN (UNII: 7EV65EAW6H)                           |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)                     |          |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)              |          |
| MINERAL OIL (UNII: T5L8T28FGP)                       |          |

**PETROLATUM** (UNII: 4T6H12BN9U)

**PROPYLPARABEN** (UNII: Z8IX2SC1OH)

**SODIUM BORATE** (UNII: 91MBZ8H3QO)

**SORBITAN SESQUIOLEATE** (UNII: 0W8RRI5W5A)

**TALC** (UNII: 7SEV7J4R1U)

**WATER** (UNII: 059QF0KO0R)

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0536-1204-73 | 1 in 1 CARTON                                      | 05/06/2019           |                    |
| 1 |                  | 113 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 05/03/2019           |                    |

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - Sheffield Pharmaceuticals, LLC (151177797)

### Establishment

| Name                           | Address | ID/FEI    | Business Operations    |
|--------------------------------|---------|-----------|------------------------|
| Sheffield Pharmaceuticals, LLC |         | 151177797 | MANUFACTURE(0536-1204) |

Revised: 5/2019

Rugby Laboratories