

EQUATE BARRIER CREAM- barrier cream cream
WALMART STORES 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.

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

<Adults: When practical, cleanse the affected area with a 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 a day.>

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 Seiquoleate, Talc, Water (Purified)

Principal Display Panel -Tube

NDC 49035-156-22

equate™



**DUAL ACTION
Barrier Cream
with Pain Relief
ANORECTAL CREAM**

ZINC OXIDE 20%
protects & soothes
irritated or chafed skin
associated with
incontinence

MENTHOL 0.45%
provides temporary
relief of pain & itching

**SOOTHING
LANOLIN**
a natural skin
moisturizer



**NET WT
4 OZ (113g)**

Drug Facts

| Active ingredients | Purpose |
|----------------------|--------------------|
| 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

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.

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.

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)

Satisfaction guaranteed - For questions or comments please call 1-888-287-1915.

DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentonville, AR 72716



NDC 49035-156-22

Equate

Dual Action Barrier Cream with Pain Relief

Anorectal Cream

Zinc Oxide 20%-Protects and soothes irritated or chafed skin associated with Incontinence

Menthol 0.45% - Provided Temporary Relief of Pain & Itching

Made in the USA

NET WT 4 oz (113g)

EQUATE BARRIER CREAM

barrier cream cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-156 |
| 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: BBL281NWFG) | |
| DISODIUM ETHYLENEDIAMINEDIACETATE (UNII: EQL53S5L0F) | |
| LANOLIN (UNII: 7EV65EAW6H) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| PROPYL PARABEN (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:49035-156-22 | 113 g in 1 TUBE; Type 0: Not a Combination Product | 02/28/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 02/28/2017 | |

Labeler - WALMART STORES INC (051957769)

Registrant - Sheffield Pharmaceuticals, LLC (151177797)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| Sheffield Pharmaceuticals, LLC | | 151177797 | manufacture(49035-156) |

Revised: 8/2017

WALMART STORES INC