MOUNTAIN ICE ECZEMA- colloidal oatmeal cream Mountainside Medical Equipment, Inc.

Mountain Ice Eczema Cream

Active Ingredients:

Colloidal oatmeal 1%

Purpose

Skin Protectant

Uses:

Temporarily protects and helps relieve minor skin irritation and itching due to:

- Eczema
- Rashes

Warnings:

For external use only.

When using this product

• avoid contact with eyes.

Stop use and ask a doctor if

- Condition worsens.
- Symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out the reach of children.

If swallowed, seek medical attention or contact a Poison Control Center immediately.

Directions:

Apply as needed. Let product rest on the skin. Avoid drying soaps that can irritate the skin. Use daily for best results.

Other information:

For use on mild to moderate eczema or as directed by a physician. Store at room temperature. Avoid freezing.

Inactive Ingredients:

Water (Aqua), Paraffinum Liquidum (Mineral) Oil, Stearyl Alcohol, Cetearyl Alcohol, Glycerin, Propylene Glycol, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Polysorbate 60, Actinidia Chinensis (Kiwi) Seed Oil, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, Sodium Hyaluronate, Hydrolyzed Collagen, Retinyl Palmitate, Ceramide NP, Ceramide AP, Ceramide EOP, Lactic Acid, Sodium Lauroyl Lactylate, Phytosphingosine, Cholesterol, Zea Mays (Corn) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Origanum Vulgare (Oregano) Oil, Curcuma Longa (Turmeric) Root Oil, Carbomer, Xanthan Gum, Citric Acid, Ethylhexylglycerin, Disodium EDTA, Sodium Hydroxide, Phenoxyethanol, Zinc Oxide (CI 77947).

Package/Label Principal Display Panel - Tube Label

MADE WITH SOLINE[®] AND SK-INFLUX[®] V MB TECHNOLOGY

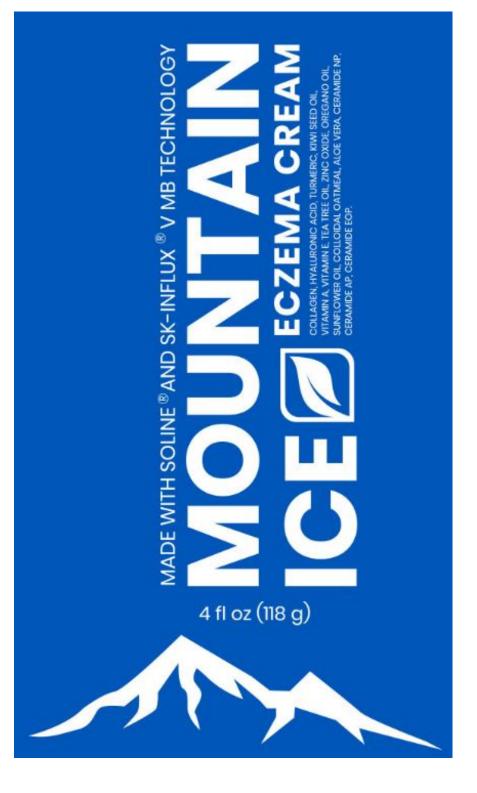
MOUNTAIN ICE ECZEMA CREAM

COLLAGEN, HYALURONIC ACID, TURMERIC, KIWI SEED OIL, VITAMIN A, VITAMIN E, TEA TREE OIL, ZINC OXIDE, OREGANO OIL, SUNFLOWER OIL, COLLOIDAL OATMEAL, ALOE VERA, CERAMIDE NP, CERAMIDE AP, CERAMIDE EOP.

4 fl oz (118 g)

Questions? 1-888-687-4334

Distributed by: Mountainside Medical 9262 Old River Road Marcy, New York 13403 Family Owned and Operated Service-Disabled Veteran



Package/Label Principal Display Panel - Packet Label

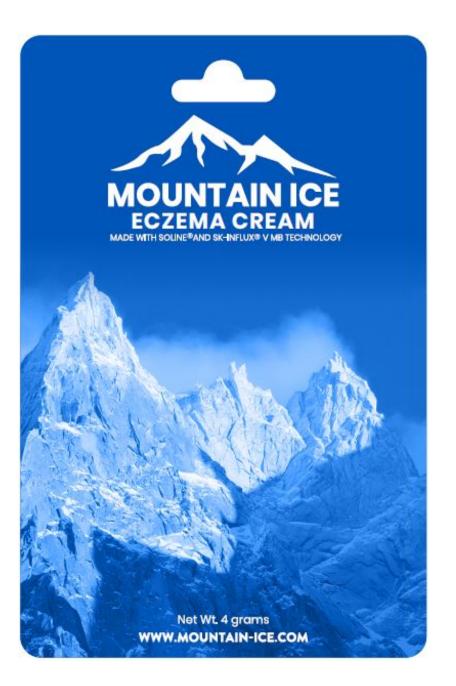
MOUNTAIN ICE ECZEMA CREAM

MADE WITH SOLINE[®] AND SK-INFLUX[®] V MB TECHNOLOGY

Net Wt. 4 grams www.MOUNTAIN-ICE.COM

Distributed by:

Mountainside Medical Marcy, New York 13403



MOUNTAIN ICE ECZEMA

colloidal oatmeal cream

| Product Information | | | | | |
|---------------------------------|----------------|-------------|------------------|--------|----------|
| Product Type | HUMAN OTC DRUG | ltem Code (| (Source) | NDC:72 | 2793-400 |
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| | | | | | |
| Active Ingredient/Active Moiety | | | | | |
| Ingredient Name | | | Basis of Strengt | th | Strength |
| | • | E | Basis of Strengt | th | Strength |

OATMEAL

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| KIWI SEED OIL (UNII: O70FW/3WPP) | |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| CERAMIDE NP (UNII: 4370DF050B) | |
| CERAMIDE AP (UNII: F1X8L2B00J) | |
| CERAMIDE 1 (UNII: 5THT33P7X7) | |
| LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) | |
| SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO) | |
| PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| CORN OIL (UNII: 8470G57WFM) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |
| OREGANO LEAF OIL (UNII: 7D0CGR40U1) | |
| TURMERIC OIL (UNII: 6KGS8SP16U) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ZINC OXIDE (UNII: SOI2LOH54Z) | |
| | |

Packaging

| # | ltem Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------------|--|-------------------------|-----------------------|
| 1 | NDC:72793-400- 01 | 118 g in 1 TUBE; Type 0: Not a Combination Product | 02/18/2021 | |
| 2 | NDC:72793-400- 02 | 4 g in 1 PACKET; Type 0: Not a Combination Product | 02/18/2021 | |
| | | | | |
| _ | | | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| | | | |

02/18/2021

Labeler - Mountainside Medical Equipment, Inc. (119735871)

| Establishment | | | | |
|-------------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Fragrance Manufacturing, Inc. | | 793406000 | MANUFACTURE(72793-400) | |

Revised: 12/2023

Mountainside Medical Equipment, Inc.