

# EVEREDEN INTENSIVE ECZEMA BALM- colloidal oatmeal ointment

## Eden Brands Inc.

### Intensive Eczema Balm

|  |   |   |  |
|--|---|---|--|
| <br>intensive eczema balm<br>baume intensif de l'eczéma | skin protectant<br>protection de la peau<br>45 g / 1.58 oz. Net Wt. | <b>Active Ingredient:</b> Colloidal Oatmeal 2% <b>Purpose:</b> Skin Protectant<br><b>DIRECTIONS:</b> Apply as needed. For external use only.<br>See outer packaging for complete Drug Facts.<br><b>WARNINGS:</b> When using this product, avoid getting into eyes.<br>Keep out of reach of children.<br>Distributed by   Distribué par © Eden Brands Inc.,<br>New York, NY 10013, United States. <a href="http://www.ever-eden.com">www.ever-eden.com</a> | <br>8 50059 70613 2 |
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Colloidal Oatmeal 2%

Skin Protectant

#### USES:

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

- Eczema
- Rashes

For external use only

When using this product: Do not get into eyes

Stop use and ask a doctor if:

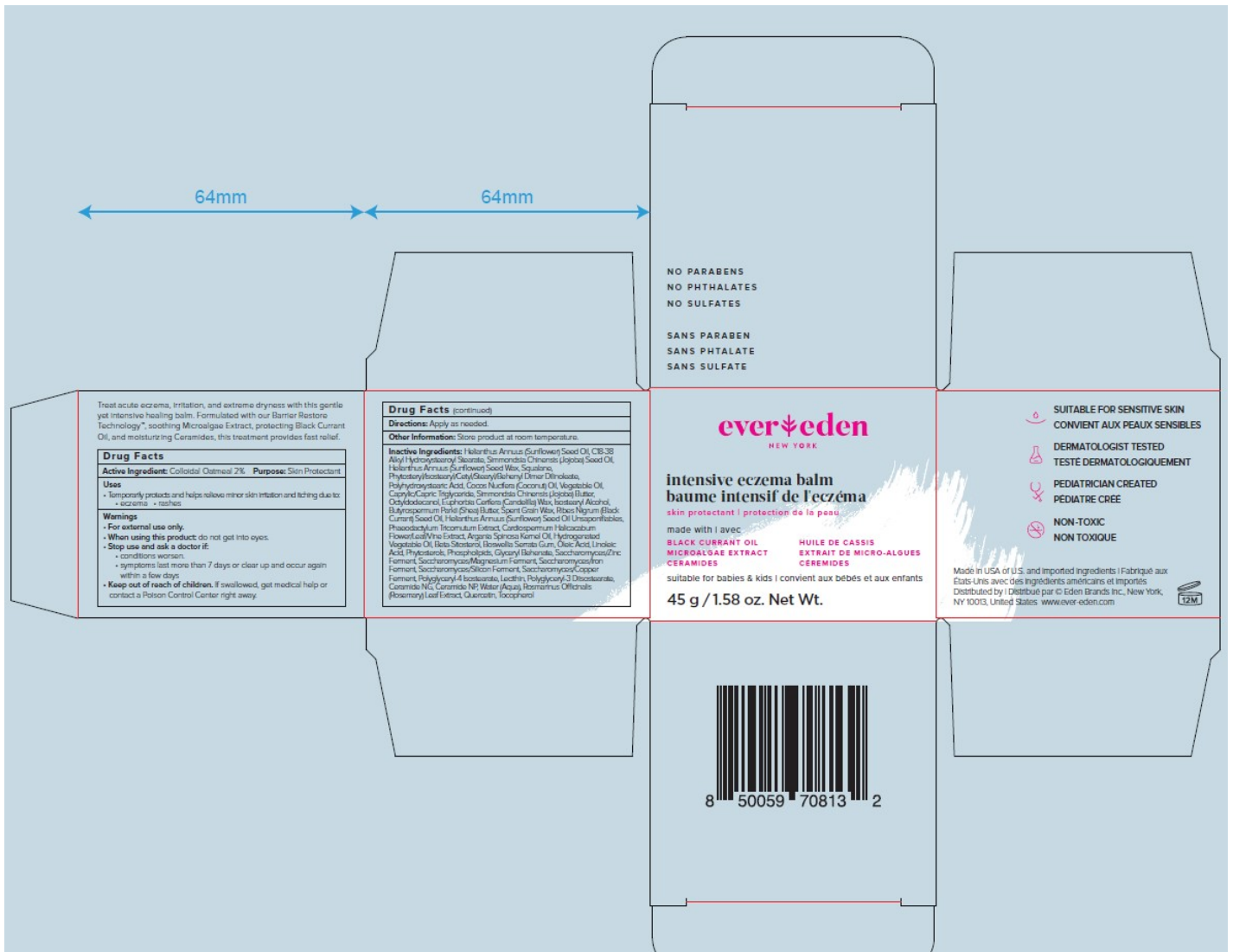
- Conditions worsen
- Symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Use as needed.

Other Information: Store product at room temperature

Helianthus Annuus (Sunflower) Seed Oil, C18-38 Alkyl Hydroxystearoyl Stearate, Simmondsia Chinensis (Jojoba) Seed Oil, Helianthus Annuus (Sunflower) Seed Wax, Squalane, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, Polyhydroxystearic Acid, Cocos Nucifera (Coconut) Oil, Vegetable Oil, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Butter, Octyldodecanol, Euphorbia Cerifera (Candelilla) Wax, Isostearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Spent Grain Wax, Ribes Nigrum (Black Currant) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Phaeodactylum Tricornutum Extract, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Argania Spinosa Kernel Oil, Hydrogenated Vegetable Oil, Beta-Sitosterol, Boswellia Serrata Gum, Oleic Acid, Linoleic Acid, Phytosterols, Phospholipids, Glyceryl Behenate, Saccharomyces/Zinc Ferment, Saccharomyces/Magnesium Ferment, Saccharomyces/Iron Ferment, Saccharomyces/Silicon Ferment, Saccharomyces/Copper Ferment, Polyglyceryl-4 Isostearate, Lecithin, Polyglyceryl-3 Diisostearate, Ceramide NG, Ceramide NP, Water (Aqua), Rosmarinus Officinalis (Rosemary) Leaf Extract, Quercetin, Tocopherol



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colloidal oatmeal ointment

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72113-109 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y) | OATMEAL           | 2 g in 100 g |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F) |          |
| <b>CANDELILLA WAX</b> (UNII: WL0328HX19)                    |          |
| <b>RIBES NIGRUM SEED OIL</b> (UNII: GKE1188837)             |          |
| <b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)               |          |

|  |
|--|
| <b>PHAEODACTYLUM TRICORNUTUM</b> (UNII: Y5W63E7HLV)                                      |
| <b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)                                     |
| <b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)   |
| <b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)   |
| <b>SUNFLOWER OIL UNSAPONIFIABLES</b> (UNII: T7ZE2WA4MB)                                  |
| <b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)                                     |
| <b>WATER</b> (UNII: 059QF0KO0R)  |
| <b>C18-38 ALKYL HYDROXYSTEAROYL STEARATE</b> (UNII: WW4FVB2PEM)                          |
| <b>.BETA.-SITOSTEROL</b> (UNII: S347WMO6M4)  |
| <b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)  |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)   |
| <b>CERAMIDE NP</b> (UNII: 4370DF050B)  |
| <b>ROSEMARY</b> (UNII: IJ67X351P9)   |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)  |
| <b>JOJOBA OIL</b> (UNII: 724GKU717M)   |
| <b>SQUALANE</b> (UNII: GW89575KF9)   |
| <b>CARDIOSPERMUM HALICACABUM LEAF</b> (UNII: 8W2E41J67L)                                 |
| <b>CORN OIL</b> (UNII: 8470G57WFM)   |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                                     |
| <b>JOJOBA BUTTER</b> (UNII: XIA46H803R)  |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)  |
| <b>ARGAN OIL</b> (UNII: 4V59G5UW9X)  |
| <b>OLEIC ACID</b> (UNII: 2UMI9U37CP)   |
| <b>LINOLEIC ACID</b> (UNII: 9KJL21T0QJ)  |
| <b>OMEGA-3 FATTY ACIDS</b> (UNII: 71M78END5S)  |
| <b>GLYCERYL DIBEHENATE</b> (UNII: R8WTH25YS2)  |
| <b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)                                   |
| <b>CERAMIDE NG</b> (UNII: C04977SRJ5)  |
| <b>QUERCETIN</b> (UNII: 9IKM0I5T1E)  |
| <b>PHYTOSTERYL/ISOSTEARYL/CETYL/STEARYL/BEHENYL DIMER DILINOLEATE</b> (UNII: 8N725H4EFN) |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)  |

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72113-109-21 | 1 in 1 CARTON                                    | 11/18/2024           |                    |
| 1 |                  | 45 g in 1 JAR; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M016                                     | 11/18/2024           |                    |

Revised: 9/2024

Eden Brands Inc.