# BABY ECZEMA THERAPY- colloidal oatmeal cream OLD EAST MAIN CO.

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.

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# Baby Eczema Therapy Cream 601.000/601AA-AB

## **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

• do not get into eyes

# Stop use and ask a doctor if

- condition worsens
- 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

apply as needed

# Other information

store at room temperature

#### Inactive ingredients

water, glycerin, distearyldimonium chloride, petrolatum, isopropl palmitate, cetyl alcohol, panthenol, dimethicone, Avena sativa (oat) kernal oil, steareth-20, Avena sativa (oat) kernal extract, benzalkonium chloride, ceramide NP, sodium chloride, benzyl alcohol, sodium hydroxide

#### disclaimer

This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, distributor of Aveeno Baby Eczema Therapy Moisturizing Cream.

## **Adverse Reactions**

DISTRIBUTED BY OLD EAST MAIN CO 100% Satisfaction Guaranteed!

## principal display panel

DG baby

Baby Eczema Therapy Cream

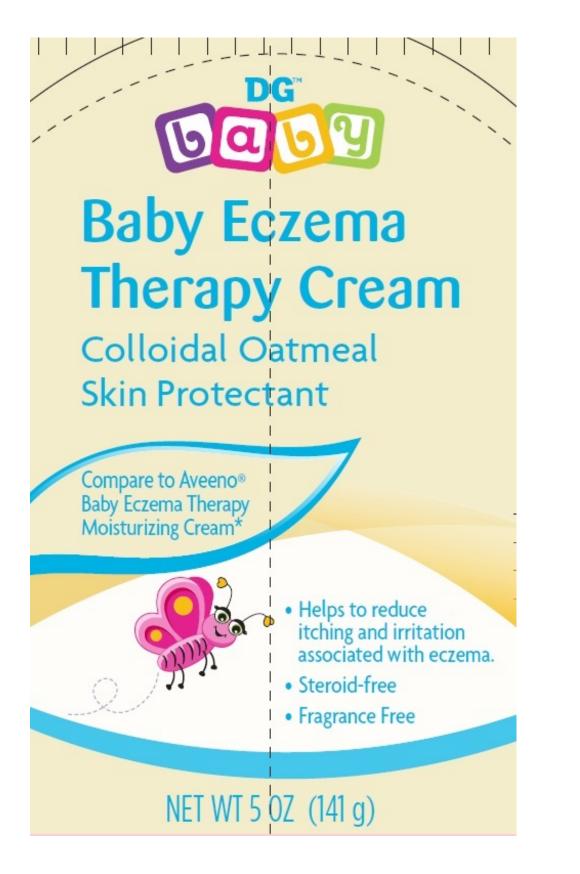
Colloidal Oatmeal Skin Protectant

Compare to Aveeno

Baby Eczema Therapy Moisturizing Cream

- Helps reduces itching and irritation associated with eczema
- Steroid Free
- Fragrance Free

NET WT 5 OZ (141g)



# principal display panel

\*Compare to Aveeno Baby Eczema Therapy Moisturizing Cream

Gentle Steps

baby

eczema

therapy

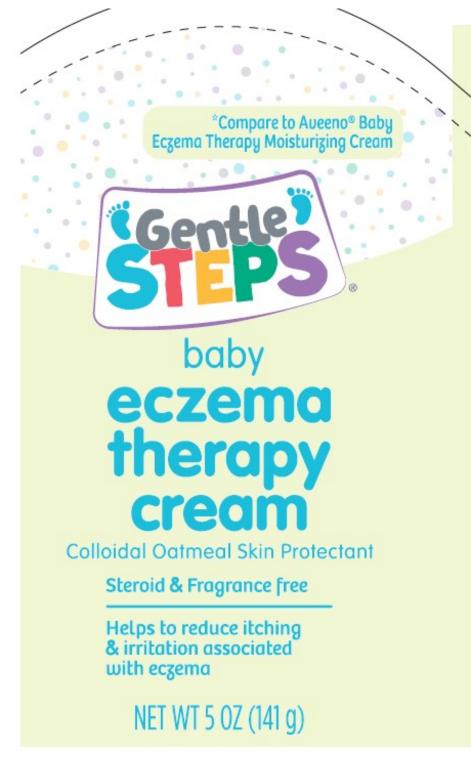
cream

Colloidal Oatmeal Skin Protectant

Steroid & Fragrance Free

Helps to reduce itching and irritation associated with eczema

NET WT 5 OZ (141)



**BABY ECZEMA THERAPY** 

| olloidal oatmea  | l cream                     |                              |        |                         |                       |  |  |
|--|-----------------------------|------------------------------|--------|-------------------------|-----------------------|--|--|
| Product Info   | rmation                     |                              |        |                         |                       |  |  |
| Product Type   |                             | HUMAN OTC DRUG               | ltem C | ode (Source)            | NDC:55910-803         |  |  |
| Route of Admin   | istration                   | TOPICAL                      |        |                         |                       |  |  |
|  |                             |                              |        |                         |                       |  |  |
| Active Ingred  | ient/Active                 | Moiety                       |        |                         |                       |  |  |
| Ingredient Name  |                             |                              |        | Basis of Streng         | th Strength           |  |  |
| oatmeal (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y) |                             |                              |        | oatmeal                 | 10.4 kg in 1 g        |  |  |
|  |                             |                              |        |                         |                       |  |  |
| Inactive Ingre   | edients                     |                              |        |                         |                       |  |  |
|  |                             | Ingredient Name              |        |                         | Strength              |  |  |
| water (UNII: 059QI                                     | F0KO0R)                     |                              |        |                         |                       |  |  |
| GLYCERIN (UNII: P                                      | DC6A3C0OX)                  |                              |        |                         |                       |  |  |
| DISTEARYLDIMON   | IUM CHLORIDI                | E (UNII: OM9573ZX3X)         |        |                         |                       |  |  |
| PETROLATUM (UN   | III: 4T6H12BN9U             |                              |        |                         |                       |  |  |
| ISOPROPYL PALM   | IITATE (UNII: 8C            | RQ2TH63M)                    |        |                         |                       |  |  |
| CETYL ALCOHOL  | (UNII: 936JST6JC            | N)                           |        |                         |                       |  |  |
| PANTHENOL (UNII  | : WV9CM0067Z)               |                              |        |                         |                       |  |  |
| DIMETHICONE (U   | NII: 92RU3N3Y1C             | ))                           |        |                         |                       |  |  |
| OAT KERNEL OIL   | (UNII: 3UVP41R7             | 7R)                          |        |                         |                       |  |  |
| BENZALKONIUM   | CHLORIDE (UNII              | : F5UM2KM3W7)                |        |                         |                       |  |  |
| CERAMIDE NP (UNII: 4370DF050B)                         |                             |                              |        |                         |                       |  |  |
| SODIUM CHLORIE   | <b>DE</b> (UNII: 451W47     | YIQ8X)                       |        |                         |                       |  |  |
| BENZYL ALCOHO  | <b>L</b> (UNII: LKG8494     | WBH)                         |        |                         |                       |  |  |
| SODIUM HYDROX  | IDE (UNII: 55X04            | QC32I)                       |        |                         |                       |  |  |
|  |                             |                              |        |                         |                       |  |  |
| Packaging  |                             |                              |        |                         |                       |  |  |
| # Item Code  | Pac                         | kage Description             |        | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| <b>1</b> NDC:55910-803-28                              | - 141 g in 1 TUE<br>Product | BE; Type 0: Not a Combinatio | on 04  | 4/11/2016               |                       |  |  |
|  |                             |                              |        |                         |                       |  |  |
| Marketing  | Informat                    | ion                          |        |                         |                       |  |  |
| Marketing  | Applica                     | tion Number or Monogr        | raph   | Marketing Start         | Marketing End         |  |  |
| Category   |                             | Citation                     |        | Date                    | Date                  |  |  |

Labeler - OLD EAST MAIN CO. (068331990)

Registrant - Vi-Jon, LLC (790752542)

| Establishment |         |           |                            |  |  |  |
|---------------|---------|-----------|----------------------------|--|--|--|
| Name          | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |
| Vi-Jon, LLC   |         | 790752542 | manufacture(55910-803)     |  |  |  |
|               |         |           |                            |  |  |  |
| Establishment |         |           |                            |  |  |  |
| Name          | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |
| Vi-Jon, LLC   |         | 088520668 | manufacture(55910-803)     |  |  |  |
|               |         |           |                            |  |  |  |

Revised: 9/2022

OLD EAST MAIN CO.