

**CETAPHIL BABY ECZEMA SOOTHING- colloidal oatmeal lotion**  
**Galderma Laboratories, L.P.**

*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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**Drug Facts**

**Active ingredients.....Purpose**

Colloidal Oatmeal 1%.....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

**Inactive Ingredients**

Allantoin, Arginine, Behenyl Alcohol, Butyrospermum Parkii, (Shea) Butter, Caprylic/Capric, Triglyceride, Caprylyl Glycol, Ceramide NP, Cetareth-20, Cetearyl Alcohol, Cetyl Alcohol, Citric Acid, Cyclopentasiloxane, Dimethiconol, Disodium EDTA, Disodium Ethylene, D cocamide PEG-15, Disulfate, Glycerin, Glyceryl Stearate, Glyceryl Stearate Citrate, Helianthus Annuus, (Sunflower) Seed Oil, Niacinamide, Panthenol, Pentylene Glycol, Sodium Hyaluronate, Sodium PCA, Sodium Polyacrylate, Sorbitol, Tocopheryl Acetate, Water

**Questions or comments?**

1-866-735-4137

Distributed By:

Galderma Laboratories, L.P.

Fort Worth, TX 76177

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Cetaphil.com

**PRINCIPLE DISPLAY PANEL**

Cetaphil®

baby

**Eczema  
Soothing  
Lotion**

Body

1% Colloidal Oatmeal

Skin Protectant

Soothes dry, itchy, irritated skin

Steroid free

Safe for babies > 3 months

5 FL OZ (147 mL)

[SEAL]

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ASSOCIATION

# Cetaphil®

## baby

### Eczema Soothing Lotion



Body

1% Colloidal Oatmeal  
Skin Protectant

Soothes dry, itchy,  
irritated skin

Steroid free

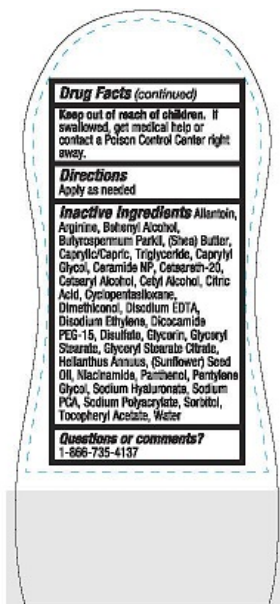
Safe for babies  
> 3 months



NATIONAL  
**Eczema**  
ASSOCIATION

P53862-0

5 FL OZ (147 mL)



## CETAPHIL BABY ECZEMA SOOTHING

colloidal oatmeal lotion

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0299-4140 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| Oatmeal (UNII: 8PI54V663Y) (Oatmeal - UNII:8PI54V663Y) | Oatmeal           | 1 g in 100 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| Allantoin (UNII: 344S277G0Z)                                    |          |
| Arginine (UNII: 94ZLA3W45F)                                     |          |
| Docosanol (UNII: 9G1OE216XY)                                    |          |
| Shea Butter (UNII: K49155WL9Y)                                  |          |
| Medium-chain Triglycerides (UNII: C9H2L21V7U)                   |          |
| Caprylyl Glycol (UNII: 00YIU5438U)                              |          |
| Ceramide 3 (UNII: 4370DF050B)                                   |          |
| Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)                |          |
| Cetostearyl Alcohol (UNII: 2DMT128M1S)                          |          |
| Cetyl Alcohol (UNII: 936JST6JCN)                                |          |
| Citric Acid Monohydrate (UNII: 2968PHW8QP)                      |          |
| Cyclomethicone 5 (UNII: 0THT5PC10R)                             |          |
| Dimethiconol (10000 Cst) (UNII: OSA9UP217S)                     |          |
| Edetate Disodium (UNII: 7FLD91C86K)                             |          |
| Disodium Ethylene Dicoamide Peg-15 Disulfate (UNII: Q19A6U005W) |          |
| Glycerin (UNII: PDC6A3C0OX)                                     |          |

|   |
|---|
| <b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)           |
| <b>Glyceryl Stearate Citrate</b> (UNII: WH8T92A065)       |
| <b>Sunflower Oil</b> (UNII: 3W1JG795YI)                   |
| <b>Niacinamide</b> (UNII: 25X51I8RD4)                     |
| <b>Panthenol</b> (UNII: WV9CM0O67Z)                       |
| <b>Pentylene Glycol</b> (UNII: 50C1307PZG)                |
| <b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)              |
| <b>Sodium Pyrrolidone Carboxylate</b> (UNII: 469OTG57A2)  |
| <b>Sodium Polyacrylate (250000 Mw)</b> (UNII: 051I5JN12J) |
| <b>Sorbitol</b> (UNII: 506T60A25R)                        |
| <b>.alpha.-tocopherol Acetate</b> (UNII: 9E8X80D2L0)      |
| <b>Water</b> (UNII: 059QF0K00R)                           |

| <b>Packaging</b> |                  |   |                      |                    |
|------------------|------------------|---|----------------------|--------------------|
| #                | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
| 1                | NDC:0299-4140-05 | 147 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/01/2018           |                    |
| 2                | NDC:0299-4140-10 | 296 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 07/22/2019           |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final          | part347                                  | 05/01/2018           |                    |

**Labeler** - Galderma Laboratories, L.P. (047350186)

| <b>Establishment</b> |         |           |                        |
|----------------------|---------|-----------|------------------------|
| Name                 | Address | ID/FEI    | Business Operations    |
| G Production Inc.    |         | 251676961 | manufacture(0299-4140) |