

**CETAPHIL ECZEMA ITCH RELIEF GEL- colloidal oatmeal gel**  
**Galderma Laboratories, L.P.**

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**Drug Facts**

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

Colloidal Oatmeal 0.5%.....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**

ARGININE, BUTYLENE GLYCOL, C13-15 ALKANE, CARBOMER, CERAMIDE NP, ETHYLHEXYLGLYCERIN, GLYCERIN, HYDROXYPHENYL PROPAMIDOBENZOIC ACID, LAURYL LACTATE, MALTODEXTRIN, OPHIOPOGON JAPONICUS ROOT EXTRACT, PENTYLENE GLYCOL, PHENOXYETHANOL, PROPANEDIOL, SODIUM GLUCONATE, SODIUM HYDROXIDE, SODIUM PCA, TOCOPHEROL (VITAMIN E), WATER, XANTHAN GUM

**Questions or comments?**

1-866-735-4137

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Galderma Laboratories, L.P.  
Dallas, TX 75201 USA

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**PRINCIPLE DISPLAY PANEL - 2 OZ carton**

Dermatologist Recommended  
For Sensitive Skin

Cetaphil®

**ECZEMA**

**RESTORADERM®**

Itch Relief Gel

**1** Relieve, **2** Repair, **3** Protect

Instantly soothes skin and relieves  
itch for up to 12 hours

**Skin Protectant Colloidal Oatmeal**

Microbiome gentle Ad-Resyl®  
Steroid free

National Eczema Association logo

2 FL OZ (59 mL)

P56603-1



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**GALDERMA**  
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STERIOD FREE

PARABEN FREE

FRAGRANCE FREE

HYPOALLERGENIC

TRUSTED BY DERMATOLOGISTS FOR 75 YEARS

COOL-TOUCH APPLICATOR

Actual Size

DERMATOLOGIST RECOMMENDED FOR SENSITIVE SKIN

**Cetaphil®**

**ECZEMA**

**RESTORADERM®**

**Itch Relief Gel**

1 Relieve 2 Repair 3 Protect

Instantly soothes skin and relieves itch for up to 12 hours

Skin Protectant Colloidal Oatmeal

Microbiome gentle Ad-Resyl®

Steroid-free

ACCEPTED  
National Eczema Association

2 FL OZ (59 mL)

LOT: EXP:

UNVARNISHED AREA

**Cetaphil® ECZEMA RESTORADERM® Itch Relief Gel**

Soothing gel with cool-touch applicator is clinically proven to provide instant and lasting relief to help break the itch-scratch cycle during eczema flare-ups.

Dermatologist developed regimen with a microbiome friendly blend of Ad-Resyl®, SymCalmin®, filaggrin technology, and skin protectant colloidal oatmeal for gentle yet effective care throughout the eczema cycle.

**5 SKIN SENSITIVITY SIGNS**

**Defends against 5 Signs of Skin Sensitivity**

- ✔ Weakened Skin Barrier
- ✔ Dryness
- ✔ Irritation
- ✔ Roughness
- ✔ Tightness

colloidal oatmeal gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0299-4129
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Oatmeal</b> (UNII: 8PI54V663Y) (Oatmeal - UNII:8PI54V663Y)	Oatmeal	0.5 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Arginine</b> (UNII: 94ZLA3W45F)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>C13-15 Alkane</b> (UNII: 114P5I43UJ)	
<b>Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked)</b> (UNII: 71DD5V995L)	
<b>Ceramide Np</b> (UNII: 4370DF050B)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>Hydroxyphenyl Propamidobenzoic Acid</b> (UNII: 25KRT26H77)	
<b>Lauryl Lactate</b> (UNII: G55U0BFK7O)	
<b>Maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>Ophiopogon Japonicus Root</b> (UNII: 90PS6JV9GZ)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Propanediol</b> (UNII: 5965N8W85T)	
<b>Sodium Gluconate</b> (UNII: R6Q3791S76)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Sodium Pyrrolidone Carboxylate</b> (UNII: 469OTG57A2)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>Water</b> (UNII: 059QF0K00R)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0299-4129-00	1 in 1 CARTON	05/01/2022	
1		59 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:0299-4129-05	10 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2022	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M016	05/01/2022	

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

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fruit of The Earth, Inc.		080086802	manufacture(0299-4129)

Revised: 12/2023

Galderma Laboratories, L.P.