

**PEDIADERMICS ECZEMA 3- colloidal oatmeal, dimethicone cream**  
**Renu Laboratories, Inc.**

*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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**pediadermics eczema 3**

**Active Ingredients**

Colloidal oatmeal 0.1%

Dimethicone 2%

**Purpose**

Skin protectant

Skin protectant

**Uses**

Temporarily protects sensitive skin and helps relieve minor skin irritation due to eczema. Temporarily helps prevent and relieve chapped or cracked skin.

**Warnings**

For external use only

**When using this product**

- Do not get into eyes
- Do not apply before bathing or showering

**Stop use and ask a doctor if**

Condition worsens

- Symptoms last more than 2 weeks 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**

For best results, follow the rule of "3"

- Apply liberally to skin at least "3" times a day
- Apply within "3" minutes of bathing
- Keep a "3" location supply (Home, On-the-Go and School) !

**Inactive Ingredients**

1,2 Hexanediol, Ascorbyl Palmitate, Bio-Saccharide 1, Candelilla / Jojoba / Rice bran, Polyglyceryl-3 Esters, Glyceryl Stearate, Cetearyl Alcohol, Sodium Stearoyl Lactylate, Caprylyl Glycol, Glycerin, Caprylhydroxamic Acid, Carbomer, Ceramide AP, Ceramide EOP, Ceramide NP, Cetyl Alcohol, Cholesterol, Deionized Water, Helianthus Annuus

(Sunflower) Seed Wax, Limnanthes Alba (Meadowfoam) Seed Oil, Niacinamide, Ophiopogon Japonicus Root Extract, Maltodextrin, Phytosphingosine, Propanediol, Saccharide Isomerate, Sodium EDTA, Sodium Hyaluronate, Sodium PCA, Stearic Acid, Tocopherol, Xanthan Gum

**Other information**

Store at room temperature.

**Questions?**

pediadermics@gmail.com

eczema 3

skin barrier repair cream



ECZEMA 3 tube artwork

<b>PEDIADERMICS ECZEMA 3</b>			
colloidal oatmeal, dimethicone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76348-580

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	3.36 g in 168 g
<b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.168 g in 168 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>RICE BRAN</b> (UNII: R60QEP13IC)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>SODIUM STEAROYL LACTYLATE</b> (UNII: IN99IT31LN)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)	
<b>BIOSACCHARIDE GUM-1</b> (UNII: BB4PU4V09H)	
<b>SODIUM LAUROYL LACTYLATE</b> (UNII: 7243K85WFO)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>CERAMIDE AP</b> (UNII: F1X8L2B00J)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HEXANEDIOL</b> (UNII: ZIA319275I)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>OPHIPOGON JAPONICUS ROOT</b> (UNII: 90PS6JV9GZ)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-580-06	168 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/01/2020	

**Labeler** - Renu Laboratories, Inc. (945739449)

## Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-580)

Revised: 1/2022

Renu Laboratories, Inc.