

GLAD SKIN ECZEMA CREAM- colloidal oatmeal lotion
Prime Enterprises

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.

GLADSKIN ECZEMA- colloidal oatmeal cream

Active Ingredient

Colloidal Oatmeal 0.02%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

Warnings

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:

- Apply twice daily, or more as desired, on skin free of other products.
- Let the cream absorb into skin for 5 minutes before applying other products.

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- Let the cream absorb into skin for 5 minutes before applying other products.

Inactive Ingredients

Water, Glycerin, Petrolatum, Mineral Oil, Cetearyl Alcohol, Cetearth-20, Arginine HCl, Sodium Chloride, Trometamol, Calcium Chloride, sr-(Methionyl Staphylococcus Simulans Polypeptide-1 Dipeptide-53 Staphylococcus Phage 2638A Polypeptide-1)*

Questions

hello@gladskin.com



- No Steroids
- No Fragrance
- No Preservatives
- No Drying Alcohols
- No Parabens
- No Sulfates

Apply twice a day
or more as desired

For best results, use by:

- 3 months from purchase if stored at room temperature, OR
- the stamped expiration date if stored in your fridge.

Do not freeze or store above 75°F.

ECZEMA Cream

With *Micreobalance*®

Hypoallergenic
Skin Protectant

100 ml | 3.4 fl. oz.



Distributed by
Microcos North America, Inc.
Encinitas, CA 92024
gladskin.com



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DRUG FACTS
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**Micreobalance*® is a proprietary smart protein that rebalances the natural skin microbiome as it moisturizes.

colloidal oatmeal lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0549
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.175 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0549-3	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/16/2020	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprise		101946028	pack(58443-0549) , manufacture(58443-0549) , analysis(58443-0549) , label(58443-0549)

Revised: 4/2022

Prime Enterprises