

ECZEMA- colloidal oatmeal lotion

Amyris, 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.

Pipette Eczema Lotion

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

Protect this product from excessive heat and direct sunlight

Inactive Ingredients

Water, Squalane, Caprylic/Capric Triglyceride, Glycerin, Hydrogenated Sunflower Seed Oil

Polyglyceryl-3

Esters, Hydroxystearic/Linolenic/Oleic Polyglycerides, Butyrospermum Parkii (Shea) Butter, Jojoba Esters.

Cetearyl Alcohol, Hydrogenated Sunflower Seed Oil Glyceryl Esters, Propanediol, Hydroxyacetophenone, Sodium Stearoyl Lactylate, Xanthan Gum, Citric Acid, Ethylhexylglycerin, Potassium Sorbate, Ceramide NP, Sodium Phytate, Tocopherol.

Dermatologist Tested • Hypoallergenic

This fragrance free, nontoxic eczema treatment is tailored for the most sensitive skin. An ultra-pure, petroleum-free blend of plant-derived ingredients gently soothes eczema flare-ups, relieves irritation and keeps dry, itchy skin calm, smooth and healthy.

Drug Facts

Active Ingredients	Purpose
Colloidal Oatmeal 1%	Skin protectant
Uses	
Temporarily protects and helps relieve minor skin irritation and itching due to:	
• Eczema flare-ups	
Warnings	
• For External Use Only	
When using this product:	
• Do not get it in eyes	
Stop use and ask a doctor if:	
• Irritation 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.	
Directions	
• Apply as needed	
Other Information Protect this product from excessive heat and direct sun.	
Inactive Ingredients Water, Glycerin, Copolymer, Polyacrylate, Cetylalcohol, Hydrogenated Sunflower Seed Oil Polyglyceryl-3 Esters, Hydroxyacetophenone, Linolenic Acid Polyglyceride, Butyrospermum Parkii (Shea) Butter, Jojoba Esters, Ceramide NP, Tocopherol, Sodium Phytate, Hydrogenated Sunflower Seed Oil Glyceryl Esters, Cetearyl Alcohol, Propanediol, Hydroxyacetophenone, Sodium Stearoyl Lactylate, Xanthan Gum, Ethylhexylglycerin, Potassium Sorbate, Citric Acid.	
Questions or comments? Call 800-747-2239	

Eczema Lotion

Fragrance Free
Relieves irritation and itching from eczema

Clean • Nontoxic • Soothing

pipette™

177 ml / 6 fl oz

Made in USA of domestic and foreign components.
Distributed by: Ampro Consumer Products, Inc. Emeryville, CA 94608

amproconsumer.com

ECZEMA

colloidal oatmeal lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73517-425

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
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER SEED OIL GLYCERETH-8 ESTERS (UNII: 358X17CAT0)	
12-HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)	
SHEA BUTTER (UNII: K49155WL9Y)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPANEDIOL (UNII: 5965N8W85T)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CERAMIDE NP (UNII: 4370DF050B)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73517-425-01	1 in 1 CARTON	02/01/2021	
1		177 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:73517-425-02	30 mL in 1 TUBE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	02/01/2021	

Labeler - Amyris, Inc (185930182)