

ROYCEDERM ECZEMA RELIEF CREAM- colloidal oatmeal 1% cream

RoyceDerm LLC

Initial Drug Listing - RoyceDerm Eczema Relief Cream

Colloidal Oatmeal 1%

Skin Protectant

Temporarily protects and helps relieve minor skin irritation and itching due to Eczema and Rashes

For external use only

do not get into eyes

condition worsens or symptoms last more than 7 days or clear up and occur again within a few days

In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away. (1-800-222-1222)

- Conduct a patch test on a small area of skin to check for sensitivity or allergic reaction.
- Apply as needed to affected area.
- Use 1-2 times daily or as directed by a doctor.
- For children under 6 months of age: ask a doctor.

store at room temperature. Avoid excessive heat and direct sunlight.

Aqua, Butylene Glycol, Glycerin, Simmondsia Chinensis (Jojoba) Seed Oil, Squalane, Camellia Japonica Seed Oil, Cetearyl Alcohol, Butyrospermum Parkii (Shea Butter), Tocopheryl Acetate, Cetearyl Glucoside, Panthenol, 1,2-Hexanediol, Hydroxyacetophenone, Ceramide 1, Ceramide 3, Ceramide 6 II, Ectoin, Carboxymethyl Chitosan, Camellia Sinensis Leaf Extract, Tremella Fuciformis Polysaccharide, Avena Sativa (Oat) Kernel Extract, Aloe Barbadensis Leaf Extract, Portulaca Oleracea Extract, Maltodextrin, Chrysanthellum Indicum Extract, Houttuynia Cordata Extract, Opuntia Streptacantha Stem Extract, Scutellaria Baicalensis Root Extract, Paeonia Suffruticosa Root Extract, Allantoin, Sodium Hyaluronate, Sodium Polyglutamate, Centella Asiatica Extract, Madecassoside, Asiaticoside

Email service@roycederm.com

Soothing Daily Relief for Eczema-Prone & Reactive Skin RoyceDerm Eczema Soothing Cream is thoughtfully formulated to calm, hydrate, and help restore balance to skin affected by: ✓ Facial eczema flare-ups, including dry patches, redness, and itching around the cheeks, chin, and forehead ✓ Sensitivity-related irritation caused by weather, masks, or over-cleansing ✓ Compromised skin barrier in delicate or reactive skin types	Eczema RELIEF CREAM Plant-Powered ✓ Non-Steroidal ✓ Sensitive Skin Approved Net Wt. 4 oz (113g)	Drug Facts Active ingredient Colloidal Oatmeal 1%.....Skin Protectant 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 and ask a doctor if condition worsens or symptoms last more than 7 days or clear up and occur again within a few days. Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away. (1-800-222-1222) Directions ■ Conduct a patch test on a small area of skin to check for sensitivity or allergic reaction. ■ Apply as needed to affected areas. ■ Use 1-2 times daily or as directed by a doctor. ■ For children under 6 months of age: ask a doctor.	Drug Facts (Continued) Other information store at room temperature. Avoid excessive heat and direct sunlight. Inactive ingredients Aqua, Butylene Glycol, Glycerin, Simmondsia Chinensis (Jojoba) Seed Oil, Squalane, Camellia Japonica Seed Oil, Cetearyl Alcohol, Butyrospermum Parkii (Shea Butter), Tocopheryl Acetate, Cetearyl Glucoside, Panthenol, 1,2-Hexanediol, Hydroxyacetophenone, Ceramide 1, Ceramide 3, Ceramide 6 II, Ectoin, Carboxymethyl Chitosan, Camellia Sinensis Leaf Extract, Tremella Fuciformis Polysaccharide, Avena Sativa (Oat) Kernel Extract, Aloe Barbadensis Leaf Extract, Portulaca Oleracea Extract, Maltodextrin, Chrysanthellum Indicum Extract, Houttuynia Cordata Extract, Opuntia Streptacantha Stem Extract, Scutellaria Baicalensis Root Extract, Paeonia Suffruticosa Root Extract, Allantoin, Sodium Hyaluronate, Sodium Polyglutamate, Centella Asiatica Extract, Madecassoside, Asiaticoside Questions or comments? Email service@roycederm.com
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ROYCEDERM ECZEMA RELIEF CREAM

colloidal oatmeal 1% cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85424-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1.13 g in 113 g

Inactive Ingredients	
Ingredient Name	Strength
AQUA (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ASIATICOSIDE (UNII: PKO39VY215)	
ALOE BARBADENSIS LEAF (UNII: ZY81Z83H0X)	
CHRYSANTHELLUM INDICUM TOP (UNII: STJ856D1Z0)	
ECTOIN (UNII: 7GXZ3858RY)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
PANTHENOL (UNII: WW9CM0O67Z)	
HOULTTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
OAT (UNII: Z6J799EAJK)	
N-CARBOXYMETHYLCHITOSAN (UNII: 5R88W82CC6)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
PURSLANE (UNII: M6S840VXG5)	
PAEONIA SUFFRUTICOSA ROOT (UNII: 7M7E9A2C8J)	
SODIUM POLYGLUTAMATE (200000 MW) (UNII: LN8DW52UVL)	
MADECASSOSIDE (UNII: CQ2F5O6YIY)	
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
CETEARYL ALCOHOL (UNII: 2DMT128M1S)	
SQUALANE (UNII: GW89575KF9)	
CAMELLIA JAPONICA SEED OIL (UNII: U37N0S910T)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	
OPUNTIA STREPTACANTHA STEM (UNII: 3TF9Z1U73O)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
TREMELLA FUCIFORMIS WHOLE (UNII: 4938BNS0GU)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ALLANTOIN (UNII: 344S277G0Z)	

CERAMIDE 3 (UNII: 4370DF050B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-010-01	113 g in 1 CARTON; Type 0: Not a Combination Product	09/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	09/30/2025	

Labeler - RoyceDerm LLC (130329531)

Registrant - RoyceDerm LLC (130329531)

Revised: 9/2025

RoyceDerm LLC