

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE LIPIKAR ECZEMA SOOTHING
RELIEF- oatmeal cream
L'Oreal USA Products 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.

Drug Facts

Active ingredient

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

Inactive ingredients

water, shea butter, glycerin, dimethicone, mineral oil, niacinamide, cetearyl alcohol, rapeseed seed oil, ammonium polyacryloyldimethyl taurate, PEG-100 stearate, glyceryl stearate, tocopherol, sodium benzoate, PEG-20 methyl glucose sesquistearate, dimethiconol, mannose, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, capryloyl glycine, microcrystalline wax, sorbitan tristearate, paraffin, disodium EDTA, vitreoscilla ferment, citric acid

Questions or comments?

1-888-LRP LABO

1-888-577-5226

Monday - Friday (9 a.m. - 5 p.m. EST)



ECZEMA-PRONE SKIN
BODY. HANDS. FACE

LIPIKAR ECZEMA

SOOTHING RELIEF CREAM
COLLOIDAL OATMEAL SKIN PROTECTANT

Clinically shown to help relieve itchy, irritated skin
Lipid replenishing, instant and lasting hydration

DERMATOLOGIST TESTED
FRAGRANCE FREE - STEROID FREE
LA ROCHE-POSAY PREBIOTIC THERMAL WATER

200 ml - 6.76 FL.OZ. Made in France

3612620756112

Lipikar Soothing Relief Cream is for dry, itchy, eczema-prone areas.
PROPERTIES. Formulated with SHEA BUTTER, AQUA POSAE FILIFORMIS, and a high concentration of LA ROCHE-POSAY PREBIOTIC THERMAL WATER used in Europe's leading center of thermal dermatology since 1905. This soothing formula also contains COLLOIDAL OATMEAL to help relieve the itching and irritation of eczema. Provides instant and up to 48hr hydration.
DERMATOLOGIST TESTED - SAFE FOR SENSITIVE SKIN.
Allergy tested. Fragrance-free. Paraben-free. Steroid-free. Non-comedogenic.

Drug Facts	
Active ingredient	Purpose
Colloidal oatmeal 1%	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	
water, shea butter, glycerin, dimethicone, mineral oil, niacinamide, cetearyl alcohol, rapeseed seed oil, ammonium polyacryloyldimethyl taurate, PEG-100 stearate, glyceryl stearate, tocopherol, sodium benzoate, PEG-20 methyl glucose sesquistearate, dimethiconol, mannose, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, capryloyl glycine, microcrystalline wax, sorbitan tristearate, paraffin, disodium EDTA, vitreoscilla ferment, citric acid	
Questions or comments?	
1-888-LRP LABO 1-888-577-5226 Monday - Friday (9 a.m. - 5 p.m. EST)	

693256 2 Code F.I.L.: D215275/1




200 ml / 6.76 FL.OZ.
Distribution reserved to La Roche-Posay
agreed distributors
La Roche-Posay LLC, 10 Hudson Yards,
New York, NY 10001
La Roche-Posay Laboratoire Dermatologique
CAJ 86270 La Roche-Posay, France
TSA 75000 93584 ST OLEN CEDEXER
www.laroche-posay.us

141 mm

Printable height: 142 mm

6

LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE LIPIKAR ECZEMA SOOTHING RELIEF

oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-621
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	10 mg in 1 mL
--	---------	---------------

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MINERAL OIL (UNII: T5L8T28FGP)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CANOLA OIL (UNII: 331KBJ17RK)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PEG-20 METHYL GLUCOSE SESQUISTEARATE (UNII: 0345752X7U)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
MANNOSE, D- (UNII: PHA4727WTP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SORBITAN TRISTEARATE (UNII: 6LUM696811)	
PARAFFIN (UNII: I9O0E3H2ZE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-621-01	1 in 1 CARTON	11/21/2017	
1		5 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-621-02	200 mL in 1 TUBE; Type 0: Not a Combination Product	11/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/21/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-621) , pack(49967-621)

Establishment

Name	Address	ID/FEI	Business Operations
BPS		272259304	pack(49967-621)

Revised: 3/2020

L'Oreal USA Products Inc