

ECZEMA CARE MOISTURIZING 3 OZ.- colloidal oatmeal lotion

Rejoice International 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.

Eczema Care Moisturizing Cream 3 oz.

Active ingredient

Colloidal Oatmeal 1%

Purpose

Skin protectant

Uses

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

Warnings

For external use only.

When using this product

- avoid contact with eyes. In case of eye contact, flush with water.

Stop using this product and ask a doctor if

- condition worsens, or if symptoms last more than 7 days, or if they clear up and occur again within a few days.

Keep out of reach of children.

- In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

Apply as needed

Other information

- store at room temperature.

Inactive ingredients

Water, Glycerin, Petrolatum, Cetearyl Alcohol, Dimethicone, Isopropyl Myristate, Distearyltrimonium Chloride, Steareth-2, Avena Sativa (Oat) Kernel Extract, Phenoxyethanol, Steareth-21, Sodium Chloride, Benzalkonium Chloride, Panthenol, Ceramide NP, Avena Sativa (Oat) Kernel Oil

Label copy



Eczema Care

Moisturizing Cream

colloidal oatmeal · skin protectant



Relieves dry, itchy, irritated skin due to eczema

Steroid-free · fragrance-free

NET WT. 3 OZ (85g)

Drug Facts

Active ingredient	Purpose
Colloidal oatmeal 1%.....	Skin protectant

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

Warnings For external use only.

When using this product avoid contact with eyes. In case of eye contact, flush with water.

Do not use on • deep or puncture wounds • animal bites • serious burns

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 immediately.

Directions Apply as needed.

Other information Store at room temperature.

Questions/Comments? 1-855-345-5575

Inactive ingredients Water, Glycerin, Petrolatum, Cetearyl Alcohol, Dimethicone, Isopropyl Myristate, Distearyl Dimonium Chloride, Steareth-2, Avena Sativa (Oat) Kernel Extract, Phenoxyethanol, Steareth-21, Sodium Chloride, Benzalkonium Chloride, Panthenol, Ceramide NP, Avena Sativa (Oat) Kernel Oil.



DISTRIBUTED BY:
REJOICE INTERNATIONAL INC.
NORTHVILLE, MI 48168, USA
MADE IN CHINA

colloidal oatmeal lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-101
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PANTHENOL (UNII: WV9CM0O67Z)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
STEARETH-20 (UNII: L0Q8IK9E08)	
OAT (UNII: Z6J799EAJK)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CERAMIDE NP (UNII: 4370DF050B)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARETH-2 (UNII: V56DFE46J5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-101-01	85 mL in 1 TUBE; Type 0: Not a Combination Product	03/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/08/2019	

Labeler - Rejoice International Inc. (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Technology Co., Ltd.		529287434	manufacture(57337-101)

Revised: 3/2019

Rejoice International Inc.