

EPIONCE RENEWAL CALMING CREAM- oatmeal cream
Episciences, 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.

Epionce Renewal Calming Cream

Active ingredient

Colloidal Oatmeal 0.03%

Purpose

Skin Protectant

Uses

- temporarily protects and helps relieve minor skin irritation and itching due to:
 - rashes
 - eczema

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply as needed

Inactive ingredients

Water, Glycerin, Petrolatum, Meadowfoam Seed Oil, Safflower Oil, PPG-2 Myristyl Ether Propionate, Hydrogenated Polybutene (1300MW), Cyclomethicone 5, Rosa Canina Fruit Oil, White Wax, Gluconolactone, Allium Fistulosum Bulb, Alteromonas Ferment Filtrate,

Apple, Arachidyl Alcohol, Arachidyl Glucoside, Butylene Glycol, C10-30 Cholesterol/Lanosterol Esters, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Carboxypolymethylene, Ceramide 1, Ceramide AP, Ceramide NP, Cetearyl Glucoside, Cetostearyl Alcohol, Cetyl Alcohol, Cholesterol, Cyclomethicone 4, Cyclomethicone 6, Dimethiconol (14000 CST), Docosanol, Edetate Disodium, Glyceryl Monostearate, Levomenol, Magnesium Salicylate, Magnesium Stearate, Manganese Gluconate, Meadowfoam Estolide, Nymphaea Alba Flower, PEG-100 Stearate, Phytosphingosine, Sodium Benzoate, Sodium Lauroyl Lactylate, Sodium Palmitoyl Proline, Trolamine, Xanthan Gum, Zinc Stearate.

Questions?

Call toll free **1-866-374-6623**

Epionce Renewal Calming Cream Principal Display Panel



CLINICAL RELIEF

SPF PROTECTANT For Dry Skin

**Renewal
Calming Cream**

Renouvellement crème apaisante

RELIEVES ECZEMA

230 g (Net Wt. 8.0 oz)

EPIONCE RENEWAL CALMING CREAM

oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42673-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
CERAMIDE AP (UNII: F1X8L2B00J)	
CERAMIDE NP (UNII: 4370DF050B)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DOCOSANOL (UNII: 9G1OE216XY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
WHITE WAX (UNII: 7G1J5DA97F)	
ALLIUM FISTULOSUM BULB (UNII: F8DD33CGGR)	
APPLE (UNII: B423VGH5S9)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35J00J)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LEVOMENOL (UNII: 24WE03BX2T)	
MAGNESIUM SALICYLATE (UNII: 41728CY7UX)	
MANGANESE GLUCONATE (UNII: 9YY2F980SV)	
NYMPHAEA ALBA FLOWER (UNII: 40KQ7Q535O)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
SODIUM PALMITOYL PROLINE (UNII: 64L053FRFO)	
TROLAMINE (UNII: 9O3K93S3TK)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ZINC STEARATE (UNII: H92E6QA4FV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42673-000-01	1 in 1 BOX	02/28/2018	12/31/2024
1	NDC:42673-000-00	30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:42673-000-03	1 in 1 BOX	02/28/2018	11/30/2024
2	NDC:42673-000-02	230 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:42673-000-04	6 g in 1 TUBE; Type 0: Not a Combination Product	02/28/2018	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/28/2018	12/31/2024

Labeler - Episciences, Inc. (144733040)

Establishment

Name	Address	ID/FEI	Business Operations
Episciences, Inc.		144733040	manufacture(42673-000)

Revised: 9/2022

Episciences, Inc.