ECZENIL - colloidal oatmeal cream Healings mith Institute 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.

Colloidal Oatmeal 2%

Skin Protectant

Uses

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

- eczema
- rashes
- insect bites
- poison ivy, oak or sumac

Warnings

For external use only.

Do not use if you are allergic to sesame oil.

When using this product

- do not get into eyes
- if you currently use steroids or have used steroids in the recent past, it may take 1 to 3 months to see results

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

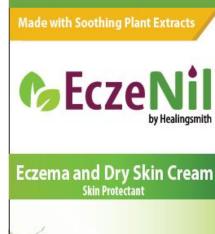
• apply twice a day or as needed

Other Information

• store in a cool and dry place

Inactive Ingredients

BHT, Cetyl Alcohol, Coccinia Indica fruit extract, Fragrance, Holarrhena Atidysenterica leaf extract, Melia Azadirachta leaf extract, Propylene Glycol, Sesamum Indicum (Sesame) seed oil, Sodium Lauryl Sulfate, Sodium Methylparaben, Sodium Propylbaraben, Stearic Acid, White soft paraffin



Temporarily protects and helps relieve dry, itching and flaking skin

- Does not contain steroids
- Safe for children
- Inspired by Ayurvedic principles

Healingsmith

Net wt 4 oz (113.2 g)



For hundreds of years, people

have used plant extracts and

natural ingredients in ancient

traditions such as Ayurveda.

Healingsmith's EczeNil Cream

maximizes the use of plant

extracts and botanical to deliver

outstanding results. It contains

the skin protectant Colloidal

Oatmeal that comforts minor

developed by Sankunnis

established in 1910.

Ayurvedic Foundatin which is

based in India. Sankunnis was

skin irritation and itching. It was

Eczema and Dry Skin Cream Skin Protectant

www.healingsmith.com

Drug Facts

Active Ingredients

Purpose

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Skin Protectant

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Lot No:

Exp Date:

Distributed by: Healingsmith Institute Inc. 12460 Crabapple Road, Ste 202-255 Alpharetta GA 30004 Made in India

www.healingsmith.com

Healingsmith's EczeNil cream uses powerful herbs and oils to soothe the skin and most people will start seeing results in just 3 to 4 applications. It can be used for Eczema, Rashes, Poison Ivy and Insect bites.

The formula is non-greasy and gets absorbed into the skin quickly. For best results, we recommend that you apply the cream at least twice a day.



Eczema and Dry Skin Cream Skin Protectant

www.healingsmith.com

ECZENIL

colloidal oatmeal cream

Product Information

HUMAN OTC DRUG NDC:76066-001 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Strength **Basis of Strength** Ingredient Name OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y) OATMEAL 2.3 g in 113.2 g

Inactive Ingredients

mactive ingredients				
Ingredient Name	Strength			
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)				
CETYL ALCOHOL (UNII: 936JST6JCN)				

COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
SESAME OIL (UNII: QX10 HYY4QV)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYLPARABEN SO DIUM (UNII: CR6 K9 C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76066-001-04	113.2 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	0 1/0 2/20 12		

Labeler - Healings mith Institute Inc. (962842642)

Registrant - Healings mith Institute Inc. (962842642)

Establishment				
Name	Address	ID/FEI	Business Operations	
Nikita Containers Private Limited		862345246	manufacture	

Revised: 10/2011 Healingsmith Institute Inc.