

ECZENIL - colloidal oatmeal cream
Healingsmith 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 Propylparaben, Stearic Acid, White soft paraffin

Made with Soothing Plant Extracts



Eczema and Dry Skin Cream
Skin Protectant

- Temporarily protects and helps relieve dry, itching and flaking skin
- Does not contain steroids
- Safe for children
- Inspired by Ayurvedic principles



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 botanicals to deliver outstanding results. It contains the skin protectant Colloidal Oatmeal that comforts minor skin irritation and itching. It was developed by Sankunnis Ayurvedic Foundation which is based in India. Sankunnis was established in 1910.



Eczema and Dry Skin Cream
Skin Protectant

www.healingsmith.com

Drug Facts

Active Ingredients	Purpose
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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

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

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ECZENIL

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76066-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
SESAME OIL (UNII: QX10HYY4QV)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PARAFFIN (UNII: I9O0E3H2ZE)	

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	01/02/2012	

Labeler - Healingsmith Institute Inc. (962842642)

Registrant - Healingsmith Institute Inc. (962842642)

Establishment

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

Revised: 10/2011

Healingsmith Institute Inc.