

## **ATOPIS ECZEMA THERAPY CREAM- colloidal oatmeal cream**

**Bionna Limited**

*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.*

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Colloidal Oatmeal 0.5%

Colloidal Oatmeal 0.5%..... Skin Protectant

temporarily protects and helps relieve minor skin irritation and itching due to • rashes • eczema • insect bites

### **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.

Apply twice daily for best results.

- Safe for the face and body.
- External use only. If irritation should occur discontinue use.
- When using this product you may notice a slight tingling sensation; this is normal and will subside.
- Do not use if quality seal is broken or missing.

Myriphytase extract (Cocos nucifera (coconut) water, Bee pollen, Cocos nucifera coconut) oil, Notofagus fuca honeydew), Cetearyl olivate, Sorbitan olivate, Carthamus tinctorius (Safflower) seed oil, Cetearyl alcohol, Glycerin, Macadamia ternifolia seed oil, Butyrospermum parkii (shea butter), Tocopheryl acetate, Sodium stearyl glutamate, benzyl alcohol, dehydracetic acid, Citrus aurantium bergamia (bergamot) fruit oil, Xanthan gum, Citric acid.

(855) 969-5002 or [contact@atopis.com](mailto:contact@atopis.com)

ATOPIS

Eczema

Therapy Cream

Skin Protectant

Cream for eczema, rash and insect bite relief

Clinically shown to relieve and protect dry, itchy, irritated skin, due to eczema

- Soothes, nourishes and restores moisture
- No parabens, no solvents, no artificial fragrances
- Clinically trialed on humans, not tested on animals

Product of New Zealand

E Net Wt 2.6 oz/75g

Clinically shown to soothe, protect and help relieve minor skin irritation and itching due to eczema.

**Drug Facts**

Active ingredient	Purpose
Colloidal Oatmeal 0.5%.....	Skin Protectant

**Uses** temporarily protects and helps relieve minor skin irritation and itching due to • rashes • eczema • insect bites

**Warnings**

For external use only

When using this product

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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 daily for best results.

**Other information**

- Safe for the face and body.
- External use only. If irritation should occur discontinue use.
- When using this product you may notice a slight tingling sensation; this is normal and will subside.
- Do not use if quality seal is broken or missing.

**Inactive ingredients**

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**Questions or comments?**

(855) 969-5002 or contact@atopis.com

Product of New Zealand

Made in the USA for Bionona Ltd.  
485B Rosebank Rd, Avondale,  
Auckland 1026, New Zealand

© ATOPIIS™

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Clinically shown to soothe, protect and help relieve minor skin irritation and itching due to eczema.

Atopis cream contains colloidal oatmeal for the temporary relief of minor skin irritation and itching due to eczema as well as the unique, scientifically-formulated Myriphytase™ extract to calm and fortify the skin, leaving skin feeling soft and smooth.

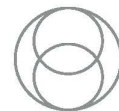
**Eczema Therapy Cream**  
Skin Protectant

Cream for eczema, rash and insect bite relief

Clinically shown to relieve and protect dry, itchy, irritated skin, due to eczema

- Soothes, nourishes and restores moisture
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Product of New Zealand  
e Net Wt 2.6 oz/75g



Nature's Scientific Skincare

e Net Wt 2.6 oz/75g



**ATOPIS ECZEMA THERAPY CREAM**

colloidal oatmeal cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71570-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
COCONUT WATER (UNII: 267F5Y81NT)	
BEE POLLEN (UNII: 3729L8MA2C)	
HONEYDEW MELON (UNII: RN8P45F92A)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BERGAMOT OIL (UNII: 39W1PKE3J1)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
MACADAMIA OIL (UNII: 515610SU8C)	
SHEA BUTTER (UNII: K49155WL9Y)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71570-001-01	1 in 1 CARTON	07/15/2019	
1		75 g in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part347	07/15/2019	
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**Labeler** - Bionona Limited (594871226)

**Establishment**

Name	Address	ID/FEI	Business Operations
I. Shay Cosmetics, Inc.		151582384	manufacture(71570-001)

Revised: 7/2019

Bionona Limited