

**ECZACALM- skin protectant ointment**  
**I Shay Cosmetics 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.*

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**EczaCalm Cream**

Organic Colloidal Oatmeal 0.8% ... Skin Protectant

Skin Protectant

WARNING: Keep out of reach of children.

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

Eczema, rashes, insect bites, poison ivy, oak or sumac

Organic Safflower Oil, Organic Beeswax, Organic Rosehip Seed Oil, Organic Flax Oil, Vitamin E From Sunflowers, Organic Horsetail, Organic Comfrey, Organic Horsetail, Organic Aloe, Organic Calendula, Organic Burdock, Organic Licorice Root, Organic Chamomile, Organic St. John's Wort, Organic Plantain.

For external use only.

Do not use on:  
deep puncture wounds  
serious burns  
animal bites

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

Apply as needed

drug panel

**Drug Facts**

Active ingredient	Purpose
Organic Colloidal Oatmeal 0.8% .....	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**  
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- deep puncture wounds
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- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

4160-HH

**POLLINATOR POWER**

— FACT —

Butterflies can detect ultraviolet light coming from flowers that are good sources of nectar.

**Drug Facts** (continued)

**Directions**  
 Apply as needed.

**Inactive ingredients**  
 Organic Safflower oil, Organic Beeswax, Organic Rosehip seed oil, Organic Flax oil, Vitamin E from Sunflowers, Organic Comfrey, Organic Aloe powder, Organic Horsetail, Organic St John's Wort oil, Organic Burdock root, Organic Calendula, Organic Chamomile, Organic Licorice root and Organic Plantain.



All sales help preserve pollinator habitat.

moonvalleyorganics.com

# ECZACALM

skin protectant ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65112-250
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.008 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	0.67 g in 1 g

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65112-250-02	1 in 1 BOX	04/01/2019	
1	NDC:65112-250-01	48.2 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part347	04/01/2019	

**Labeler** - I Shay Cosmetics Inc (151582384)

Revised: 10/2022

I Shay Cosmetics Inc