

**FLEXITOL FACE AND EYELID ECZEMA- oatmeal cream**  
**LaCorium Health USA 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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**Flexitol® Face & Eyelid Eczema Cream**

**Drug Facts**

**Active ingredient**

Colloidal Oatmeal 5%

**Purpose**

Skin protectant

**Uses**

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

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

**Warnings**

**For external use only**

**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

**When using this product** do not get into eyes

**Do not use** on broken skin

**Keep out of reach of children.**

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

**Directions**

apply generously to affected areas as needed

**Other Information**

Store between 50-86°F in a dry place

### **Inactive ingredients**

aloe barbadensis leaf juice powder, benzyl alcohol, butyrospermum parkii (shea) butter, caprylyl glycol, cetostearyl alcohol, decyl oleate, dehydroxanthan gum, glycerin, glyceryl stearate se, isopropyl myristate, water

### **Questions or Comments?**

Call Toll Free 1-866-478-3338

**usainfo@flexitol.com**

**www.flexitol.com**

### **DISTRIBUTED BY:**

**LaCorium Health USA Inc**

801 Broad St, Suite 600

Chattanooga, TN 37402

### **PRINCIPAL DISPLAY PANEL - 40 g Tube Carton**

NDC: 43251-4904-1

Flexitol®

FACE &  
EYELID  
ECZEMA  
CREAM

SOOTHING RELIEF  
FOR DELICATE SKIN

HELPS RELIEVE RED, ITCHY,  
ECZEMA RASHES ON FACE  
& EYELIDS

WITH SOOTHING COLLOIDAL  
OATMEAL 5%

FREE FROM CORTISONE

SKIN PROTECTANT

HYPOALLERGENIC

Proud Supporter  
eczema  
association  
australia  
eaa

Net Wt. 1.4 oz (40g)



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SOOTHING RELIEF  
FOR DELICATE  
SKIN

FLEXITOL FACE & EYELID  
ECZEMA CREAM

is uniquely formulated to help  
relieve symptoms associated with  
eczema on the delicate  
skin of face and eyelids.

Suitable for sensitive skin and  
children, Flexitol Face & Eyelid  
Eczema Cream is formulated  
with colloidal oatmeal, well  
known for its ability to soothe  
the most delicate skin gently  
and effectively.

Free from cortisone, artificial  
fragrances and colors, this  
intensive moisturizing cream  
leaves the skin feeling soft, not  
greasy or with visible residue.

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**MANUFACTURED FOR:**  
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101 Grafton Street,  
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NSW 2022, Australia  
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dehydroxanthan gum, glycerin,  
glyceryl stearate se, isopropyl  
myristate, water

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VFA

# FLEXITOL FACE AND EYELID ECZEMA

oatmeal cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43251-4904
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
oatmeal (UNII: 8PI54V663Y) (oatmeal - UNII:8PI54V663Y)	oatmeal	50 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
Water (UNII: 059QF0KO0R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
DECYL OLEATE (UNII: ZGR06DO97T)	
Glycerin (UNII: PDC6A3C0OX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SHEA BUTTER (UNII: K49155WL9Y)	
Caprylyl glycol (UNII: 00YIU5438U)	
Dehydroxanthan gum (UNII: 63ZP711BQO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43251-4904-1	1 in 1 CARTON	01/01/2022	
1		40 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	01/01/2022	

**Labeler** - LaCorium Health USA Inc. (111254392)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ross Laboratories Aust Pty Ltd		753529114	MANUFACTURE(43251-4904) , LABEL(43251-4904) , ANALYSIS(43251-4904) , PACK(43251-4904)

Revised: 5/2022

LaCorium Health USA Inc.