FLEXITOL HAPPY LITTLE BODIES ECZEMA RELIEF- oatmeal cream LaCorium Health USA Inc

Flexitol[®] Happy Little Bodies[™] Eczema Relief Cream

Drug Facts

Active ingredient

Colloidal Oatmeal 5%

Purpose

Skin protectant

Uses

temporarily protects and relieves minor skin irritation and itching due to:

- eczema
- dermatitis
- rashes

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
- If contact occurs, rinse eyes thoroughly with water.
- wait 15 minutes. If redness or swelling occurs, discontinue use.

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 as needed to affected skin 2-3 times a day
- smooth in gently
- the smallest effective dose should be used
- patch test recommended on sensitive skin

Other Information

Store between 50-86°F in a dry place

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, calendula officinalis flower extract, cetearyl alcohol, ceteth-20, dimethicone, disodium EDTA, glycerin, glyceryl caprylate, glyceryl stearate, hydroxyacetophenone, isopropyl myristate, mineral oil, phenoxyethanol, sodium stearoyl glutamate, triethanolamine, water

Questions or Comments?

Call Toll Free 1-866-478-3338

usainfo@flexitol.com www.flexitol.com

PRINCIPAL DISPLAY PANEL - 56 g Tube Carton

NDC 43251-4927-1

Flexitol®

happy little bodies™

ECZEMA RELIEF

CREAM

SOOTHES RASHES & FLARE-UPS

Gentle Formula Skin Protectant Cream with colloidal oatmeal 5%

Proud Supporter eczema association australasia eaa

Net Wt. 2 oz (56 g)

16 **SOOTHES RASHES** & FLARE-UPS

NDC 43251-4927-1 **Flexitol**®

happy little bodies **ECZEMA** RELIEF CREAM

SOOTHES RASHES & FLARE-UPS

Gentle Formula

- 45

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Skin Protectant Cream with colloidal oatmeal 5%



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happy little bodies **ECZEMA**

SOOTHES RASHES & FLARE-UPS

Gentle Formula

Skin Protectant Cream with colloidal oatmeal 5%



Net Wt. 2 oz (56 g)

Managing eczema prone skin in kids is a challenge that parents face day to day. Keeping your child's skin eczema free and managing flare-ups requires more than just an eczema cream - it requires a regimen of care.

FLEXITOL® HAPPY LITTLE BODIES

ECZEMA RELIEF CREAM is formulated with effective and gentle ingredients to provide relief from skin irritation, itching, flaking and dryness. Flexitol Happy Little **Bodies Eczema Relief Cream** contains colloidal oatmeal, known to help relieve itching and scratchy rashes, minor skin irritations, redness and dry skin patches. Fortified with calendula officinalis to soothe and calm irritation and aloe vera to help nourish and moisturize dry, flaky

Designed to temporarily protect and relieve symptoms associated with eczema, specifically for babies and young children, Flexitol Happy Little Bodies Eczema Relief Cream:

- Contains 5% colloidal oatmeal for relief of itching & dryness

 Calms & soothes irritated skin,
 rashes and flare-ups

 Is free from cortisone, artificial
- colors and fragrances, parabens, coal tar, pine tar and nut oils

For best results, use in conjunction with Flexitol Happy Little Bodies Body Wash & Shampoo, a soap-free alternative to harsh shampoos and soaps, to help prevent dryness.

USA DISTRIBUTOR: LaCorlum Health USA Inc 801 Broad St, Suite 600 Chattanooga, TN 37402 Call Toll Free 1-866-478-3338

LaCorlum Health International Pty Ltd Level 14, Tower 2, 101 Grafton Street, Bondi Junction, NSW 2022, Australia





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FLEXITOL HAPPY LITTLE BODIES ECZEMA RELIEF

oatmeal cream

Product	Inform	ation

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
oatmeal (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	oatmeal	50 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
Aloe Vera Leaf (UNII: ZY81Z83H0X)		
Water (UNII: 059QF0KO0R)		
Carbomer Interpolymer type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)		
Calendula Officinalis Flower (UNII: P0M7O4Y7YD)		
Cetostearyl Alcohol (UNII: 2DMT128M1S)		
Ceteth-20 (UNII: I835H2IHHX)		
Dimethicone (UNII: 92RU3N3Y10)		
Edetate Disodium (UNII: 7FLD91C86K)		
Glyceryl Monocaprylate (UNII: TM2TZD4G4A)		
Glyceryl Monostearate (UNII: 2300U9XXE4)		
Glycerin (UNII: PDC6A3C0OX)		
Hydroxyacetophenone (UNII: G1L3HT4CMH)		
Isopropyl Myristate (UNII: 0RE8K4LNJS)		
Mineral Oil (UNII: T5L8T28FGP)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
Trolamine (UNII: 903K93S3TK)		
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43251- 4927-1	1 in 1 CARTON	01/02/2022	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43251- 4927-2	1 g in 1 PACKET; Type 0: Not a Combination Product	01/02/2022	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

Labeler - LaCorium Health USA Inc (111254392)

Establishment			
Name	Address	ID/FEI	Business Operations
Bentley Laboratories, LLC		068351753	MANUFACTURE(43251-4927)

Revised: 5/2024 LaCorium Health USA Inc