

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, ceteryl alcohol, ceteth-20, dimethicone, disodium EDTA, glycerin, glyceryl caprylate, glyceryl stearate, hydroxyacetophenone, isopropyl myristate, mineral oil, phenoxyethanol, sodium stearyl glutamate, triethanolamine, water

Questions or Comments?

Call Toll Free 1-866-478-3338

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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)



FLEXITOL HAPPY LITTLE BODIES ECZEMA RELIEF

oatmeal cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43251-4927 |
| 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: 059QF0K00R) | |
| Carbomer Interpolymer type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO) | |
| Calendula Officinalis Flower (UNII: P0M7O4Y7YD) | |
| Cetostearyl Alcohol (UNII: 2DMT128M1S) | |
| Ceteth-20 (UNII: I835H2IHHX) | |
| Dimethicone (UNII: 92RU3N3Y1O) | |
| Edetate Disodium (UNII: 7FLD91C86K) | |
| Glyceryl Monocaprylate (UNII: TM2TZD4G4A) | |
| Glyceryl Monostearate (UNII: 230OU9XXE4) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Hydroxyacetophenone (UNII: G1L3HT4CMH) | |
| Isopropyl Myristate (UNII: 0RE8K4LNJS) | |
| Mineral Oil (UNII: T5L8T28FGP) | |
| Phenoxyethanol (UNII: HIE492ZZ3T) | |
| Trolamine (UNII: 9O3K93S3TK) | |
| 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 Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
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OTC Monograph Drug M016

11/29/2021

Labeler - LaCorium Health USA Inc (111254392)

Revised: 12/2023

LaCorium Health USA Inc