

AMERIDERM DERMAFIX- lanolin ointment
Shield Line LLC

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.

DRUG FACTS

Active Ingredient

Lanolin 22%

Purpose

Skin Protectant

Uses

- Helps prevent and temporarily protects chafed, chapped, or cracked skin
- Temporarily protects minor: ■ cuts ■ cuts ■ scrapes ■ burns

Warnings

FOR EXTERNAL USE ONLY

When using this product

- Avoid contact with eyes ■ If eye contact occurs, flush with water

Stop use and ask a doctor if

- condition worsens
- symptoms last more than seven days or clear up and occur again within several days

Do not use on

- deep or puncture wounds
- lacerations ■ animal bites
- serious burns

Keep out of reach of children

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

Directions

Apply as needed to clean skin twice daily or more often if necessary ■ For children under 6 months ask a doctor

Inactive Ingredients

Aluminum Hydroxide, Alpha Tocopherol Acetate (Vitamin E), Calcium Carbonate, Cholecalciferol (Vitamin D3), Citric Acid, Corn Oil, Ethylparaben, Lanolin Alcohols, Magnesium Hydroxide, Methylparaben, Sodium Chloride, Sodium Laureth Sulfate, Petrolatum, Vitamin A Palmitate, Water, Zinc Chloride

Product Label

AmeriDerm
DermaFixTM
Ointment
■ Skin Protectant

NDC: 52410-8050-3
Reorder #: 405
4 OZ. (113 GRAMS)

Drug Facts

Active Ingredient
Lanolin 2%.....Skin Protectant

Uses
■ Helps prevent and temporarily protects chapped, chipped or cracked skin
■ Temporarily protects minor: ■ cuts ■ scrapes ■ burns

Warnings
FOR EXTERNAL USE ONLY
When using this product
■ Avoid contact with eyes
■ If eye contact occurs, flush with water

Stop use and ask a doctor if
■ condition worsens
■ symptoms do not improve or become more severe
■ if rash or other skin condition occurs again within several days

Do not use on
■ legs or pressure wounds
■ lacerations ■ animal bites
■ serious burns

Keep out of reach of children
If swallowed, get medical help or contact a Poison Control Center right away.

Directions
Apply as needed to clean skin twice daily or more often if necessary
■ For children under 6 months, ask a doctor

Inactive Ingredients
Aluminum Hydroxide,
Alpha-Tocopherol Acetate (Vitamin E),
Calcium Carbonate, Cholecalciferol
(Vitamin D3), Citric Acid, Corn Oil,
Ethylparaben, Lanolin Alcohols,
Magnesium Hydroxide, Methylparaben,
Sodium Chloride, Sodium Laureth
Sulfate, Petrolatum, Vitamin A
Palmitate, Water, Zinc Chloride

Room #: _____
Name: _____

Manufactured for
Shield Line LLC
Hickensack, NJ 07601
www.ameriderm.com
Made in India 3C-80503AD-01

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AMERIDERM DERMAFIX

lanolin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52410-8050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN OIL (UNII: 8470G57WFM)	
ETHYLPARABEN (UNII: 14255EXE39)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
PETROLATUM (UNII: 4T6H12BN9U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
WATER (UNII: 059QF0K00R)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52410-8050-3	113 g in 1 JAR; Type 0: Not a Combination Product	02/01/2015	
2	NDC:52410-8050-2	113 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2015	

Labeler - Shield Line LLC (078518916)

Revised: 10/2016

Shield Line LLC