DERMADROX- aluminum hydroxide ointment
GERITREX 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.

Dermadrox Ointment

Drug Facts

Active Ingredients Purpose

Aluminum Hydroxide 1.2% A Skin protectant

Intended Use

Used for relief of minor skin irritations such as chafing, Interigo and galling.

Provides temporary relief to abraded skin, friction burns and rubbing.

Lubricates effectively on psoriatic skin.

Effective for dried cracked skin, sunburn and abraded skin

Directions

Apply liberally as often as necessary to minor burns, abraded skin,

irritated areas and minor wounds.

Reapply at least every 12 hours.

Warnings

For External Use Only

Avoid contact with eyes

Discontinue use if symptoms persist for more than 7 days.

DERMADROX ointment is contraindicated in patients with a

history of hypersensitivity to any of its components.

Inactive Ingredients

Calcium Carbonate, Citric acid, Deionized water, Glycerin, Lanolin, Lanolin Alcohol,

Mangnesium hydroxide, Methyl and propyl parabens, Mineral oil, Petrolatum,

Sodium chloride, Sodium laureth sulfate, Stearyl alcohol, Vitamin A and D in a

Hydrophilic ointment base, Zinc chloride.

Keep out of reach of children

Store at room temperature (59'F-86'F).

Keep lid tightly closed.

Reapply at least every 12 hours

54162-221-01

Geritrex®

DERMADROX

OINTMENT

pH Balanced

Skin Protectorant

Fragrance Free

Dermatologist Recommended

NET WT 4 oz. (113 gm)

Geritrex®
Geritrex Corporation
144 Kingsbridge Road East
Mount Vernon, NY 10550
1-800-736-3437
www.geritrex.com

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- Reapply at least every 12 hours.

Inactive Ingredients

Calcium Carbonate, Citric Acid, Deionized Water, Glycerin, Lanolin, Lanolin Alcohol, Magnesium Hydroxide, Methyl and Propyl Parabens, Mineral Oil, Petrolatum, Sodium Chloride, Sodium Laureth Sulfate, Stearyl Alcohol, Vitamin A & D in a Hydrophilic ointment base, Zinc Chloride.

Storage

Store at room temperature (59°F-86°F).
Keep lid tightly closed.

N 3 54162-22101 9 C12

DERMADROX

aluminum hydroxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-221
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	1.356 g in 113 g

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
VITAMIN A (UNII: 81G40H8B0T)	
VITAMIN D (UNII: 9VU1KI44GP)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54162-221-01	113 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/31/2015	

Labeler - GERITREX LLC (112796248)

Registrant - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-221)