DERMADROX- aluminum hydroxide ointment GERITREX CORP

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

DERMADROX

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pH Balanced

Skin **Protectorant**

> **Fragrance** Free

Dermatologist Recommended

NET WT 4 oz. (113 gm)



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.



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DERMADROX

aluminum hydroxide ointment

Prod	net	Info	rma	tion
P FOU				

HUMAN OTC DRUG LABEL NDC:54162-221 Product Type Item Code (Source)

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALUMINUM HYDRO XIDE (ALUMINUM HYDRO XIDE)	ALUMINUM HYDRO XIDE	1.2 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM CARBONATE			
CITRIC ACID ACETATE			
WATER			
GLYCERIN			
LANOLIN			
LANOLIN ALCOHOLS			
MAGNESIUM HYDRO XIDE			
METHYLPARABEN			
PROPYLPARABEN			
MINERAL O IL			
PETROLATUM			
SO DIUM CHLO RIDE			
SO DIUM LAURETH SULFATE			
STEARYL ALCOHOL			
VITAMIN A			
VITAMIN D			
ZINC CHLORIDE			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-221-01	113 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part346	0 1/30/20 13		

Labeler - GERITREX CORP (112796248)

Registrant - GERITREX CORP (112796248)

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

Revised: 1/2013 GERITREX CORP