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 Gel	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

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, Magnesium Hydroxide, Mineral Oil,

Petrolatum, Sodium Chloride, Sodium Laureth Sulfate, Stearyl Alcohol, Vitamin A and D, Zinc Chloride

Keep out of reach of children

Storage

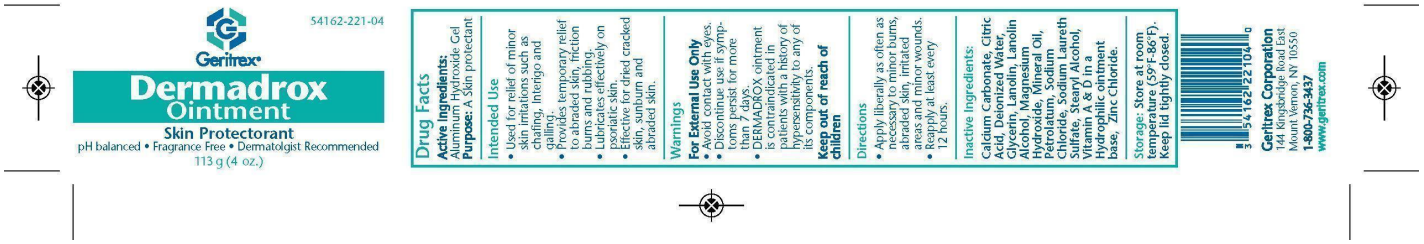
Store at room temperature (59'F-86'F) Keep lid tightly closed

Reapply at least every 12 hours

Direction

Apply liberally as often as necessary to minor burns, abraded skin, irritated areas and minor wounds

Reapply at least every 12 hours



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)	
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:54162-221-04	113 g in 1 JAR; 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	10/15/2013	

Labeler - GERITREX LLC (112796248)

Registrant - GERITREX LLC (112796248)

Establishment

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

Revised: 10/2016 GERITREX LLC