

**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.*

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**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, Magnesium 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

Tube Length 150 mm

NDC 54162-221-01



# Dermadrox Ointment

## Skin Protectant

NET WT. 4oz (113g) • pH Balanced • Fragrance Free • Dermatologist Recommended



<b>Drug Facts</b>
<b>Active Ingredient</b> Aluminum Hydroxide 1.2%.....A Skin protectant
<b>Purpose</b>
<b>Uses</b>
<ul style="list-style-type: none"> <li>■ Dress the oozing, and weeping of poison ivy, poison oak, or poison sumac.</li> <li>■ For the temporary protection, comfort and lubrication of minor skin irritations such as intertrigo, chafing, galling, rubbing or friction.</li> </ul>
<b>Warnings</b>
For external use only. Avoid contact with eyes.
Not to be applied over deep or puncture wounds, infections or lacerations. <b>Consult a physician.</b>
If condition worsens or does not improve within 7 days stop use and <b>consult a physician.</b>
<b>Do not use on</b> children under 6 months of age without consulting a physician.
<b>Keep this and all medicines out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> Cleanse area and dry thoroughly. Apply as needed, directly to the affected area.
<b>Other information</b>
<ul style="list-style-type: none"> <li>■ Store at Controlled Room Temperature 15°-30°C (59°-86°F).</li> </ul>
<b>Inactive ingredients</b>
Calcium Carbonate, Citric Acid, DMDM Hydantoin, Glycerin, Lanolin, Lanolin Alcohol, Magnesium Hydroxide, Methyl Paraben, Mineral Oil, Petrolatum, Propyl Paraben, Sodium Chloride, Sodium Laureth Sulfate, Stearyl Alcohol, Vitamin A Palmitate, Water, Zinc Chloride.

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Printing Area 135 mm

### 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 HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	1.356 g in 113 g

## Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
WATER (UNII: 059QF0K00R)	
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: 2KR89I4HIY)	
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)