

DERMADROX- zinc acetate spray
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 Spray

Active
Zinc Acetate 0.45%

Purpose:

Skin protectant/Astringent

Intended Use:

Rehydrates damaged tissues and protects chaffed, chapped, cracked, or burned skin.

Warnings:

For External Use Only Discontinue use if symptoms persist for more than 7 days and consult a physician

Do not use on children under 6 years of age without consulting a physician

KEEP OUT OF REACH OF CHILDREN

Avoid contact with eyes

Directions

Apply generously as often as necessary to minor burns, abraded skin, irritated areas and minor wounds. Spray directly on the affected area with a thin coat of Dermadrox. Reapply at least every 12 hours. May be used as a wet dressing.

Inactive Ingredients

Alcohol, Citric Acid, Corn Syrup, Purified Water, Pyridoxine HCL, Sodium Benzoate, Sodium Chloride

54162-220-14



Geritrex®

Dermadrox

Moisturizing Spray Skin Protectant

Fragrance Free

No Animal Testing

Latex Free

118 ml. (4 fl. oz.)

Drug Facts	
Active Ingredients	Purpose
Zinc acetate 0.45%	Skin Protectant, Astringent
Intended Use: Rehydrates damaged tissues and protects chafed, chapped, cracked or burned skin.	
Warnings	
For External Use Only	
<ul style="list-style-type: none"> • Discontinue use if symptoms persist for more than 7 days and consult a physician. • Do not use on children under 6 yrs of age without consulting the physician. 	
Keep out of reach of children.	
Avoid Contact with eyes.	
Directions	
<ul style="list-style-type: none"> • Apply generously as often as necessary to minor burns, abraded skin, irritated areas and minor wounds. • Spray directly on the affected area with a thin coat of Dermadrox™. • Reapply at least every 12 hrs. May be used as a wet dressing. 	
Inactive Ingredients: Alcohol, Citric acid, Corn syrup, Purified Water, Pyridoxine HCL, Sodium Benzoate and Sodium Chloride.	
Storage: At controlled room temperature 20°-25° C (68°-77°F).	



Geritrex®

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zinc acetate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.531 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
WATER (UNII: 059QF0KO0R)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-220-14	118 mL in 1 BOTTLE, SPRAY; 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)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-220)

Revised: 7/2015

Geritrex LLC