

DERMA GRAN - zinc acetate spray
Derma Sciences Canada, Inc.

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.

Drug Facts

Active ingredient:

Zinc Acetate 0.1%

Purpose

Protectant

Uses:

Protects and rehydrates damaged tissue due to rubbing or friction.

Warnings

For external use only.

Do not use on

children under 2 years of age without consulting a physician.

Discontinue use if symptoms persist more than 7 days, and consult a physician.

Avoid contact with eyes.

Keep this and all medicines out of children's reach.

Directions

- Apply liberally as often as necessary to abraded skin and irritated areas.
- Do not wipe, allow to dry.

Other Ingredients:

Alcohol (denatured), Glucose, Methylparaben, Propylparaben, Purified water, Pyridoxine hydrochloride, Sodium chloride, Zinc chloride, Zinc sulfate.

Store at Controlled Room Temperature 15-30 C (59-86 F).

Principal Display Panel

DERMA SCiENCES™

NDC 64772-127-52

DERMA GRAN®

MOISTURIZING SPRAY

pH Balanced

Skin Protectant

DM-4

REORDER No.

Net Contents 4 fl oz (118 mL)

Made in Canada

Derma Sciences, Inc., 104 Shorting Road, Toronto

Ontario M1S 3S4 Canada

Questions: In U.S.A. call 1-800-445-7627

In Canada call: 1-800-387-5302

Visit our web site at: www.dermasciences.com

U.S. Patent Number 4,847,083

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(04-10)

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DERMA GRAN

zinc acetate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64772-127
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DEXTROSE (UNII: IY9XDZ35W2)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
ZINC SULFATE (UNII: 89DS0H96TB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64772-127-52	118 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/20/2015	

Labeler - Derma Sciences Canada, Inc. (200564891)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Sciences Canada, Inc.		200564891	manufacture(64772-127)

Revised: 4/2015

Derma Sciences Canada, Inc.