DERMA GRAN - aluminium hydroxide ointment
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 Ingredients:

Aluminium Hydroxide Gel 0.275%

Purpose

Skin Protectant

Uses:

- Dries the oozing, and weeping of poison ivy, poison oak, or poison sumac.
- For the temporary protection, comfort and lubrication of minor skin irritations such as intertrigo, chafing, galling, rubbing or friction.

Warnings:

For external use only.

Avoid contact with eyes.

Not to be applied over deep or puncture wounds, infections or lacerations. **Consult a physician.**

If condition worsens or does not improve within 7 days stop use and **consult a physician.**

Do not use on

children under 6 months of age without consulting a physician.

Keep this and all medicines out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Cleanse area and dry thoroughly. Apply as needed, directly to the affected area.

Other Ingredients:

Calcium carbonate, Lanolin, Magnesium hydroxide, Methlyparaben, Petrolatum, Propylene glycol, Propylparaben, Sodium Chloride, Sodium Lauryl Sulfate, Stearyl alcohol, Vitamin A Palmitate, Water, Zinc Chloride.

Customer Storage:

Store at a Controlled Room Temperature 15-30°(59-86°F)

Principal Display Panel

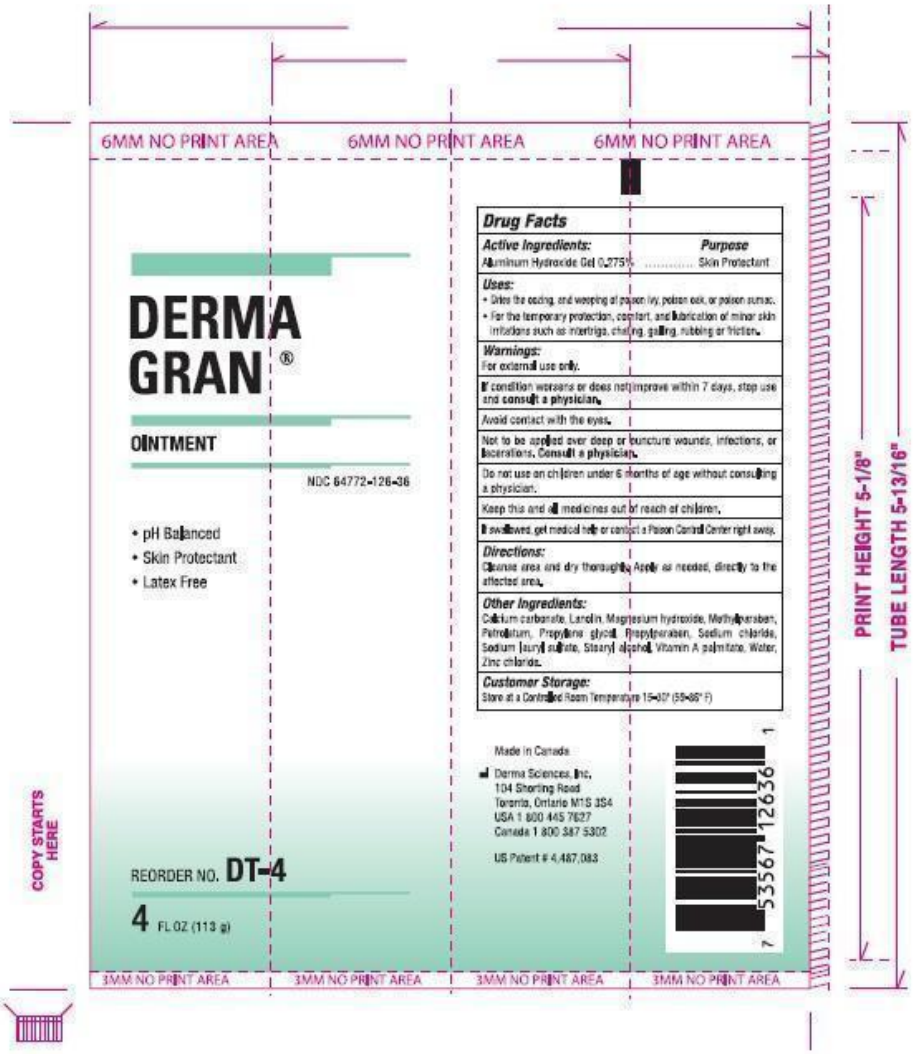
DERMA GRAN

OINTMENT

NDC 64772-126-36

- pH Balanced
- Skin Protectant
- Latex Free

4 FL OZ (113 g)



DERMA GRAN

OINTMENT

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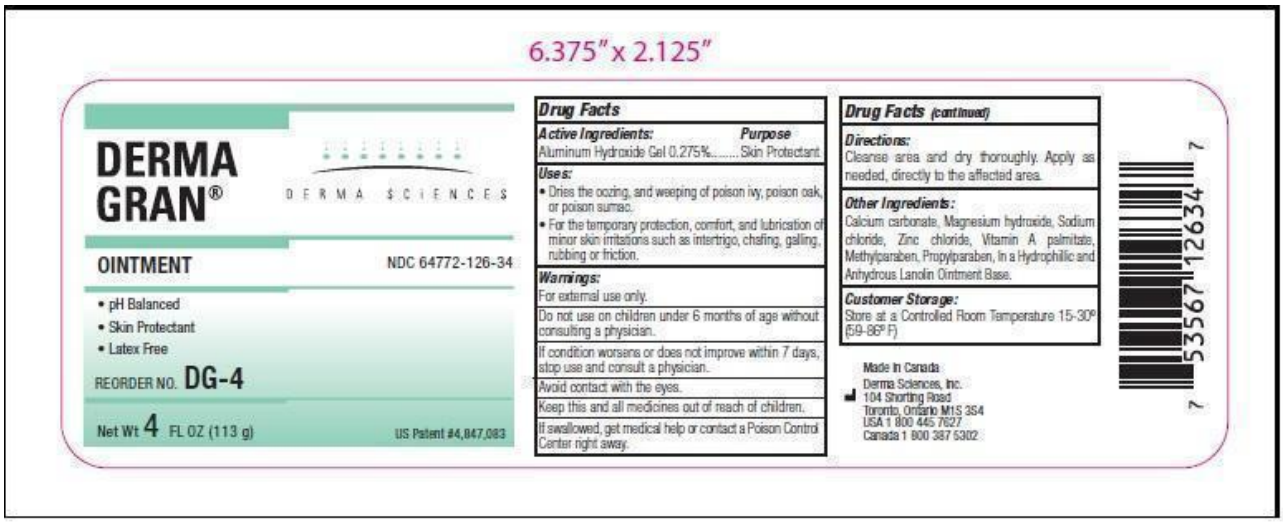

DERMA GRAN

aluminium hydroxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64772-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALGELDRATE (UNII: 03J11K103C) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALGELDRATE	0.275 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
LANOLIN (UNII: 7EV65EAW6H)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
WATER (UNII: 059QF0KO0R)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64772-126-36	113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:64772-126-34	113 g in 1 JAR; 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	06/16/2015	

Labeler - Derma Sciences Canada, Inc. (200564891)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Sciences Canada, Inc.		200564891	manufacture(64772-126)

Revised: 6/2015 Derma Sciences Canada, Inc.