

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)

6MM NO PRINT AREA 6MM NO PRINT AREA 6MM NO PRINT AREA

DERMA GRAN[®]

OINTMENT

NDC 64772-126-36

- pH Balanced
- Skin Protectant
- Latex Free

REORDER NO. **DT-4**

4 FL.OZ (113 g)

Drug Facts

Active Ingredients:	Purpose
Aluminum Hydroxide Gel (0.275%)	Skin Protectant

Uses:

- After 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 insect bites, chafing, galling, rubbing or friction.

Warnings:

For external use only.

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

Avoid contact with the eyes.

Not to be applied over deep or laceration wounds, infections, or lacerations. 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, Methylparaben, Petroleum, 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)

Made in Canada

Derma Sciences, Inc.,
104 Sherling Road
Toronto, Ontario M1S 3S4
USA 1 800 445 7627
Canada 1 800 387 5302

US Patent # 4,487,083



PRINT HEIGHT 5-1/8" TUBE LENGTH 5-13/16"

3MM NO PRINT AREA 3MM NO PRINT AREA 3MM NO PRINT AREA 3MM NO PRINT AREA

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DERMA GRAN
OINTMENT
NDC 64771-126-34

- pH Balanced
- Skin Protectant
- Latex Free

6.375" x 2.125"

**DERMA
GRAN®**



OINTMENT

NDC 64772-126-34

- pH Balanced
- Skin Protectant
- Latex Free

REORDER NO. **DG-4**

Net Wt **4** FL OZ (113 g)

US Patent #4,047,083

Drug Facts

Active Ingredients: Aluminum 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.
Do not use on children under 6 months of age without consulting a physician.

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

Avoid contact with the eyes.
Keep this and all medicines out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

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

Other Ingredients:
Calcium carbonate, Magnesium hydroxide, Sodium chloride, Zinc chloride, Vitamin A palmitate, Methylparaben, Propylparaben, in a Hydrophilic and Anhydrous Lanolin Ointment Base.

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

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Toronto, Ontario M1S 3S4
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Canada 1 800 387 5302



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: 2KR89I4HIY)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
WATER (UNII: 059QF0K00R)				
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.