

**ASTONEAGRAN- aluminium hydroxide ointment**  
**ASTONEA LABS PRIVATE LIMITED**

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**ASTONEA Gran**

**Active Ingredients:**

Aluminium Hydroxide Gel 2 % w/w

**Purpose**

Skin Protectant

**Uses:**

- Dries the oozing, and weeping of poison ivy, poison oak, or poison sumac, or other skin irritations

**Warnings:**

For external use only.

■ Deep or puncture wounds ■ Animal bites ■ Serious burns

Avoid contact with eyes. In case of contact, flush thoroughly with water

**Stop use and ask a doctor if**

■ Condition worsens

■ Symptoms last more than 7 days or clear up and occur again within a few days

**Keep out of reach of children**

In case of accidental ingestion contact a physician or Poison Control Center right away

**Directions**

Apply liberally to affected area as needed or as directed by a physician ■ Children under 6 months: ask a doctor

**Other Information**

■ Store at room temperature 15°-30°C (59°-86°F)

Calcium Carbonate, Cholecalciferol, Citric Acid, DMDM Hydantoin, Ethylhexylglycerin, Lanolin, Lanolin Alcohol, Magnesium Hydroxide, Petrolatum, Phenoxyethanol, Propylene Glycol, Purified Water, Retinyl Palmitate, Sodium Chloride, Sodium Laureth Sulfate, Stearyl Alcohol, Zea Mays Corn Oil, Zinc Chloride

## **Principal Display Panel**

| <b>Drug Facts</b>  |                                   |
|--|-----------------------------------|
| <b>Active Ingredient</b><br>Aluminum Hydroxide Gel 2% w/w  | <b>Purpose</b><br>Skin Protectant |
| <b>Uses</b> ■ Dries the oozing and weeping of poison: ■ Ivy<br>■ Oak ■ Sumac, or other skin irritations  |                                   |
| <b>Warnings</b> ■ For external use only  |                                   |
| <b>Do not use on</b> ■ Deep or puncture wounds ■ Animal bites ■ Serious burns  |                                   |
| ■ <b>Avoid contact with eyes.</b> In case of contact, flush thoroughly with water  |                                   |
| <b>Stop use and ask a doctor if</b> ■ Condition worsens ■ Symptoms last more than 7 days or clear up and occur again within a few days   |                                   |
| <b>Keep out of reach of children.</b><br>In case of accidental ingestion contact a physician or Poison Control Center right away   |                                   |
| <b>Directions</b><br>■ Apply liberally to affected area as needed or as directed by a physician ■ <b>Children under 6 months: ask a doctor</b>   |                                   |
| <b>Other Information</b><br>■ Store at room temperature 15°-30°C (59°-86°F)  |                                   |
| <b>Inactive Ingredients</b><br>Calcium Carbonate, Cholecalciferol, Citric Acid, DMDM Hydantoin, Ethylhexylglycerin, Lanolin, Lanolin Alcohol, Magnesium Hydroxide, Petrolatum, Phenoxyethanol, Propylene Glycol, Purified Water, Retinyl Palmitate, Sodium Chloride, Sodium Laureth Sulfate, Stearyl Alcohol, Zea Mays Corn Oil, Zinc Chloride |                                   |

Patient Name:  
Room #:

**ASTONEA**

**Skin  
Protectant**

with Aluminum Hydroxide Gel

**Manufactured by:**  
Astonea Labs Private Limited  
Village Haripur, Tehsil Raipurani,  
Near Mouli Police Station,  
Panchkula, Haryana,  
India - 134204

HR/DRUGS 1105-OSPI(H)

SOOTHES AND  
PROMOTES HEALING

4 Oz. (113g)

**ASTONEAGRAN**

aluminium hydroxide ointment

**Product Information**

|  |   |  |                             |                           |
|--|---|--|-----------------------------|---------------------------|
| <b>Product Type</b>  | HUMAN OTC DRUG                                  | <b>Item Code (Source)</b>                          | NDC:77338-021               |                           |
| <b>Route of Administration</b>   | TOPICAL   |  |                             |                           |
| <b>Active Ingredient/Active Moiety</b>                                       |   |  |                             |                           |
| <b>Ingredient Name</b>   |   | <b>Basis of Strength</b>                           | <b>Strength</b>             |                           |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0) |   | ALUMINUM HYDROXIDE                                 | 2 g<br>in 100 g             |                           |
| <b>Inactive Ingredients</b>  |   |  |                             |                           |
| <b>Ingredient Name</b>   |   |  | <b>Strength</b>             |                           |
| CALCIUM CARBONATE (UNII: H0G9379FGK)   |   |  |                             |                           |
| LANOLIN (UNII: 7EV65EAW6H)   |   |  |                             |                           |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)                                     |   |  |                             |                           |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)                                       |   |  |                             |                           |
| PETROLATUM (UNII: 4T6H12BN9U)  |   |  |                             |                           |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)  |   |  |                             |                           |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)   |   |  |                             |                           |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0)                                    |   |  |                             |                           |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y)   |   |  |                             |                           |
| WATER (UNII: 059QF0KO0R)   |   |  |                             |                           |
| ZINC CHLORIDE (UNII: 86Q357L16B)   |   |  |                             |                           |
| DMDM HYDANTOIN (UNII: BYR0546TOW)  |   |  |                             |                           |
| CORN OIL (UNII: 8470G57WFM)  |   |  |                             |                           |
| CHOLECALCIFEROL (UNII: 1C6V77QF41)   |   |  |                             |                           |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)  |   |  |                             |                           |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)                                       |   |  |                             |                           |
| LANOLIN ALCOHOLS (UNII: 884C3FA9HE)  |   |  |                             |                           |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)  |   |  |                             |                           |
| <b>Packaging</b>   |   |  |                             |                           |
| <b>#</b>   | <b>Item Code</b>                                | <b>Package Description</b>                         | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1  | NDC:77338-021-23                                | 113 g in 1 TUBE; Type 0: Not a Combination Product | 08/18/2022                  |                           |
| <b>Marketing Information</b>   |   |  |                             |                           |
| <b>Marketing Category</b>  | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b>                        | <b>Marketing End Date</b>   |                           |
| OTC Monograph Drug   | M016  | 08/17/2022   |                             |                           |

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)

