

**ASTONEA EXTRA STRENGTH ANTI-ITCH CREAM ITCH STOPPING-  
diphenhydramine hydrochloride and zinc acetate cream  
ASTONEA LABS PRIVATE LIMITED**

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**ASTONEA Extra Strength Anti-Itch Cream**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Diphenhydramine hydrochloride 2%	Topical analgesic
Zinc acetate 0.1%	Skin protectant

**Uses**

- temporarily relieves pain and itching associated with:
  - insect bites
  - minor burns
  - sunburn
  - minor skin irritations
  - minor cuts
  - scrapes
  - minor skin irritations
  - rashes due to poison ivy, poison oak, oak, and sumac
- dries the oozing and weeping of poison ivy, poison oak, and poison sumac

**Warnings**

For external use only

Do not use

- **on large areas of the body**
- **with any other product containing diphenhydramine, even one taken by mouth**

Ask a doctor before use

- **on chicken pox**
- **on measles**

When using this product

- **use only as directed**
- **avoid contact with eyes**

Stop use and ask a doctor if

- **condition worsens or does not improve within 7 days**
- **symptoms persist for more than 7 days or clear up and occur again within a few days**

Keep out of reach of children. **If swallowed, get medical help or contact a Poison**

Control Center right away. (1-800-222-1222)

## Directions

- adults and children 2 years of age and over: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician

## Other information

- store at 20°C-25°C (68°C/77°F)
- do not use if tube seal under cap is broken

## Inactive ingredients

Ceteth-20, Cetostearyl Alcohol, Chlorocresol, Edetate disodium, Light Mineral Oil, Petrolatum, Propylene Glycol, Sodium metabisulfite, Water

## ASTONEA Extra Strength Anti-Itch Cream

**ASTONEA**

**Extra OTC Strength  
Anti-Itch Cream**

DIPHENHYDRAMINE HYDROCHLORIDE • ZINC ACETATE

NET WT 1.25 OZ (35.4g)

<b>Drug Facts</b> <b>Active ingredients</b> Diphenhydramine hydrochloride 2% ..... Topical analgesic Zinc acetate 0.1% ..... Skin protectant	<b>Purpose</b> Skin protectant
<b>Uses</b> temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: ■ insect bites ■ minor burns ■ sunburn ■ minor cuts ■ scrapes ■ minor skin irritations ■ rashes due to poison ivy, oak, sumac ■ dries the oozing and weeping of poison ivy, poison oak and poison sumac	
<b>Warnings</b> For external use only Do not use ■ on large areas of the body ■ with any other product containing diphenhydramine, even one taken by mouth Ask a doctor before use ■ on chicken pox ■ on measles When using this product ■ use only as directed ■ avoid contact with eyes	
<b>Drug Facts (continued)</b> 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. If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
<b>Directions</b> ■ adults and children 2 years of age and over: apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a physician.	
<b>Other Information</b> ■ store at 20°-25°C (68°-77°F) ■ do not use if tube seal under cap is broken	
<b>Inactive ingredients</b> ceteth-20, cetostearyl alcohol, chlorocresol, edetate disodium, light mineral oil, petrolatum, propylene glycol, sodium metabisulfite, water	

HD DRUGS 1105-GSP(H)

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

**ASTONEA EXTRA STRENGTH ANTI-ITCH CREAM ITCH STOPPING**  
diphenhydramine hydrochloride and zinc acetate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-215
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	20 mg in 1 g
<b>ZINC ACETATE</b> (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CHLOROCRESOL</b> (UNII: 36W5307109)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77338-215-01	1 in 1 CARTON	09/01/2021	
1		35.4 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	09/01/2021	

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