

ATOPALM ITCH RELIEF - diphenhydramine hydrochloride, zinc acetate cream
Neopharm Co, Ltd

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.

Atopalm Itch Relief Cream

Active Ingredient

Diphenhydramine HCl 2%

Zinc Acetate 0.1%

Purpose

Topical Analgesic

Skin protectant

Uses

For the temporary relief of itching and pain associated with

insect bites

minor burns

sunburn

minor skin irritations

minor cuts

scrapes

rashes due to poison ivy, poison oak and poison 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 or with any other product containing Diphenhydramine, even one taken by mouth.

Ask a doctor before use on chicken pox or measles.

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

condition worsens or does not improve within 7 days, or if 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 immediately.

Directions

adults and children 2 years of age and older, apply to affected area no more than 3 to 4 times daily, or as directed by a doctor.

children under 2 years of age, consult a doctor.

do not use more often than directed

Other information

store between 20C to 25C (69F to 77F)

see end of carton or tube crimp for lot number and expiration date.

Inactive Ingredients

Water, Glycerin, Cetyl Alcohol, Mineral Oil, Polysorbate 60, Stearic Acid, Glyceryl stearate, Carbomer 940, Cholesterol, Methylparaben, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, propylparaben.

Questions?

Call 1-855-ATOPALM

ATOPALM ITCH RELIEF CREAM

with US Patented MLE Technology

MAXIMUM STRENGTH THERAPY
TOPICAL ANALGESIC

HISTAMINE BLOCKER
SKIN PROTECTANT

For fast, temporary relief of pain and itching from insect bites and skin irritations from poison ivy, poison oak, and poison sumac, dries up poison ivy, poison oak, and poison sumac. Leaves skin looking visibly healthier, softer, smoother.

ATOPALM
Histamine Blocker
Topical Analgesic
Skin protectant

Net Wt. 1oz/28.3 g

ITCH RELIEF CREAM

ATOPALM[®]

Drug Facts

| | |
|---------------------------------|-------------------|
| Active Ingredients | Purpose |
| Diphenhydramine HCl 2% | Topical Analgesic |
| Zinc Acetate 0.1% | Skin Protectant |

Uses

■ for the temporary relief of itching and pain associated with: ■ insect bites ■ minor burns ■ sunburn ■ minor skin irritations ■ minor cuts ■ scrapes ■ rashes due to poison ivy, poison oak and poison 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 or with any other product containing Diphenhydramine, even one taken by mouth.

Ask a doctor before use on chicken pox or measles.

When using this product avoid contact with the eyes.

Stop use and ask a doctor if condition worsens or does not improve within 7 days, or if symptoms persist for more than 7 days or clear up and occur again within a few days. ▶

Drug Facts (continued)

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

Directions

- **adults and children 2 years of age and older**, apply to affected area: not more than 3 to 4 times daily, or as directed by a doctor.
- **children under 2 years of age**, consult a doctor
- do not use more often than directed.

Other Information

- store between 20° to 25°C (68° to 77°F)
- see end of carton or tube crimp for lot number and expiration date.

Inactive Ingredients

Water, Glycerin, Cetyl Alcohol, Mineral Oil, Polysorbate 60, Stearic Acid, Glyceryl Stearate, Carbomer 940, Cholesterol, Methylparaben, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, Propylparaben

Questions? Call 1-855-ATOPALM

US Patent # US 6221371B1

Distributed by: NeoPharm USA, 1 Oyster Bay Drive, Rumson, NJ 07760

Made in Korea

75716



ATOPALM[®]

Net Wt. 1 oz / 28.3 g

ITCH RELIEF

US PATENTED MILE TECHNOLOGY

US PATENTED MILE TECHNOLOGY

NDC 51141-4000-1



Fast Acting Itch Relief

✓ For fast, temporary relief of pain and itching from insect bites and skin irritations from poison ivy, poison oak and poison sumac, dries up poison iv, poison oak and poison sumac. Leaves skin looking visibly healthier, softer smoother

Maximum Strength ■ Histamin Blocker ■ Topical Analgesic ■ Skin Protectant

ATOPALM®

Cream based on
US patented MLE technology

Diphenhydramine Hydrochloride 2%

ITCH RELIEF

Net Wt. 1 oz / 28.3 g

ATOPALM®

ATOPALM ITCH RELIEF

diphenhydramine hydrochloride, zinc acetate cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51141-4000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|-------------------|
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 2 g in 100 g |
| ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37) | ZINC ACETATE | 0.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| MYRISTOYL/PALMITOYL OXOSTEARAMIDE/ARACHAMIDE MEA (UNII: 1211AIM8G7) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:51141-4000-1 | 1 in 1 BOX | | |
| 1 | | 28.3 g in 1 TUBE; 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 | 03/16/2011 | |

Labeler - Neopharm Co, Ltd (965502912)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|-------------------------|
| NeoPharm Co., Ltd. | | 631101883 | manufacture(51141-4000) |

Revised: 6/2015

Neopharm Co, Ltd