

ANTI-ITCH CREAM- diphenhydramine hydrochloride 2%, zinc acetate 0.1% cream

Trifecta Pharmaceuticals USA, LLC.

Anti-Itch Cream

Active Ingredient

Diphenhydramine Hydrochloride 2%

Purpose

Topical Analgesic

Active Ingredient

Zinc Acetate 0.1%

Purpose

Skin Protectant

For the temporary relief from pain and itching associated with

- insect bites
- minor burns
- minor skin irritation
- rashes due to poison ivy, poison oak, and poison sumac
- dries the weeping and oozing of poison ivy, oak and 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 eyes

Stop use and ask a doctor if

- Conditions worsen or do not improve within 7 days
- Symptoms persist for more than 7 days or clear up and occur again within a few days

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- Conditions worsen or do not improve within 7 days

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Keep out of the reach of children

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Do not use more than directed
- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: consult a doctor

Other information

- Store at controlled room temperature 20°-25°C (68°-77°F)
- Close cap tightly after use

Questions? Call 1-888-296-9067

Inactive Ingredients

Aloe Vera (Aloe Barbadensis) leaf juice, Cetyl alcohol, Glyceryl monostearate, Methylparaben, Mineral Oil, Petrolatum, Polyoxyethylene lauryl ether, Propylene glycol, Propylparaben, Purified Water, Stearic acid

Distributed By:

Trifecta Pharmaceuticals USA, LLC.

101 NE Third Avenue, Suite 1500

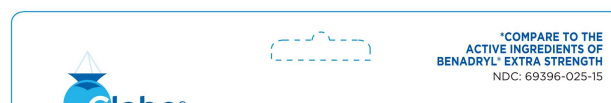
Ft. Lauderdale, FL. 33301 USA

Product of PRC

www.trifecta-pharma.com

Packaging

OUTSIDE BOX



Relieves Itching from Insect Bites and Skin Irritations

EXTRA STRENGTH

Histamine Blocking Relief from:
Poison Ivy • Poison Oak
Poison Sumac • Insect Bites
Mosquito Bites, Sunburn, and Minor Cuts & Scrapes

Itch Stopping Cream
TOPICAL ANALGESIC & SKIN PROTECTANT

Not Wt. 1.5 oz. (42g) **EXTRA STRENGTH**

Globe®
Itch Stopping Cream
TOPICAL ANALGESIC
& SKIN PROTECTANT

Distributed by:
Triecta Pharmaceuticals USA®
101 NE Third Avenue, Suite 1500
FL Lauderdale, FL 33301 USA
www.triecta-pharma.com

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100% GUARANTEED

Itch Stopping Cream
TOPICAL ANALGESIC & SKIN PROTECTANT

LOT:
EXP:

Drug Facts (continued)	<p>Active Ingredients Diphenhydramine hydrochloride 2% Zinc Acetate 0.1% Purpose Topical Analgesic Skin Protectant</p> <p>Uses Temporarily relieves pain and itching associated with: • insect bites • minor burns • sunburn • minor skin irritations • minor cuts • scrapes • rashes due to poison ivy, poison oak, and poison sumac</p> <p>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 children, face, or mouth. When using this product, avoid contact with eyes. Stop use and ask a doctor if: • Conditions worsen or do not improve within 7 days</p> <p>Stop use and ask a doctor if</p> <p>Keep out of the reach of children • Symptoms persist for more than 7 days or clear up and occur again within a few days</p> <p>Directions • Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age: consult a doctor.</p> <p>Other Information • Store at controlled room temperature 20°-25°C (68°-77°F). • Close cap tightly after use.</p> <p>Inactive Ingredients Active ingredients: Benzyl Alcohol, Propylene Glycol, Polyethylene Glycol, Propylene Glycol, Propylene Glycol, Purified Water, Stearic Acid</p> <p>Questions? Call 1-888-286-9987</p>
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INNER TUBE

NDC: 69396-025-15

Globe® Itch Stopping Cream
TOPICAL ANALGESIC & SKIN PROTECTANT

Not Wt. 1.5 oz. (42g) **EXTRA STRENGTH**

<p>Active Ingredients Diphenhydramine hydrochloride 2% Zinc Acetate 0.1% Purpose Topical Analgesic Skin Protectant</p> <p>Uses Temporarily relieves pain and itching associated with: • insect bites • minor burns • sunburn • minor skin irritations • minor cuts • scrapes • rashes due to poison ivy, poison oak, and poison sumac</p> <p>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 children, face, or mouth. When using this product, avoid contact with eyes.</p> <p>Directions • Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age: consult a doctor.</p> <p>Other Information • Store at controlled room temperature 20°-25°C (68°-77°F). • Close cap tightly after use.</p> <p>Inactive Ingredients Active ingredients: Benzyl Alcohol, Propylene Glycol, Polyethylene Glycol, Propylene Glycol, Purified Water, Stearic Acid</p> <p>Questions? Call 1-888-286-9987</p>	<p>Stop use and ask a doctor if • Conditions worsen or do not improve within 7 days • Symptoms persist for more than 7 days or clear up and occur again within a few days</p> <p>Keep out of the reach of children</p> <p>Directions • Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age: consult a doctor.</p> <p>Other Information • Store at controlled room temperature 20°-25°C (68°-77°F). • Close cap tightly after use.</p> <p>Inactive Ingredients Active ingredients: Benzyl Alcohol, Propylene Glycol, Polyethylene Glycol, Propylene Glycol, Purified Water, Stearic Acid</p> <p>Questions? Call 1-888-286-9987</p>
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ANTI-ITCH CREAM

diphenhydramine hydrochloride 2%, zinc acetate 0.1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-025
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
LAURETH-23 (UNII: N72LMW566G)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-025-05	1 in 1 BOX	12/29/2016	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-025-15	1 in 1 BOX	02/11/2020	
2		42 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 Drug	M017	12/29/2016	

Labeler - Trifecta Pharmaceuticals USA, LLC. (079424163)

