

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

Chain Drug Marketing Association 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.

Quality Choice Extra Strength 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 1-800-935-2362

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

Distributed by CDMA Inc.

43157 W 9 Mile Road

Novi, MI 48375

www.qualitychoice.com

Questions: 800-935-2362

Product of PRC

This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company owner of the registered trademark Benadryl.

Packaging

OUTSIDE BOX



NDC 63868-683-01

*Compare to the active ingredients in BENADRYL®

Extra Strength Anti-Itch Cream

Topical Analgesic - Itching & Pain Relief

Diphenhydramine Hydrochloride 2% | Antihistamine
Zinc Acetate 0.1% | Skin Protectant

Histamine Blocking Relief from:
Poison Ivy • Poison Oak
Poison Sumac • Insect Bites



Extra Strength
Anti-Itch Cream
Topical Analgesic - Itching & Pain Relief





1 oz (Net Wt 28.3 g)

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Distributed by C.D.M.A., Inc.®
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

Product of PRC

LOT:
EXP:

Drug Facts (continued)	Drug Facts
Active ingredient	Diphenhydramine hydrochloride 2%.....Topical Analgesic Zinc Acetate 0.1%.....Skin Protectant
Purpose	Topical Analgesic Skin Protectant
Keep out of the reach of children.	
Directions	For the temporary relief from pain and itching associated with: • insect bites • minor burns • minor skin irritation • rashes • 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 Do not use more than directed
Warnings	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: • Symptoms worsen or do not improve within 7 days • Conditions persist for more than 7 days or clear up and occur again within a few days
For external use only	
Other information	Store at controlled room temperature 20°-25°C (68°-77°F) • Close cap tightly after use
Inactive ingredients	Aloe barbadensis leaf juice, Cetyl alcohol, Glycerol monostearate, Methylparaben, Mineral oil, Petrolatum, Polyoxyethylene lauryl ether, Propylene glycol, Purified water, Stearic acid

INNER TUBE



*Compare to the active ingredients in BENADRYL®

Extra Strength Anti-Itch Cream

Topical Analgesic - Itching & Pain Relief

Diphenhydramine Hydrochloride 2% | Antihistamine
Zinc Acetate 0.1% | Skin Protectant

1 oz (Net Wt 28.3 g)

Active ingredient
Diphenhydramine hydrochloride 2%.....Topical Analgesic
Zinc Acetate 0.1%.....Skin Protectant

Purpose
Topical Analgesic
Skin Protectant

Uses: 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

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

Inactive ingredients Aloe barbadensis leaf juice, Cetyl alcohol, Glycerol monostearate, Methylparaben, Mineral oil, Petrolatum, Polyoxyethylene lauryl ether, Propylene glycol, Propylparaben, Purified water, Stearic acid

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Important information - read carefully
 • Symptoms persist for more than 7 days or clear up and occur again within a few days
 Keep out of the reach of children.


 43527 W 9 Mile Rd
 Novi, MI 48375
 www.qualitychoice.com
 Durskington 800-935-2362
 Product of PRC

ANTI-ITCH CREAM

diphenhydramine hydrochloride 2%, zinc acetate 0.1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-683
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)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-683-01	1 in 1 BOX	08/14/2020	
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	08/14/2020	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 5/2023

Chain Drug Marketing Association Inc.