

TOPCARE ANTI ITCH- diphenhydramine hydrochloride, zinc acetate cream
Topco Associates LLC

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.

Topco Associates LLC. Anti-Itch Cream 2% Drug Facts

Active ingredients

Diphenhydramine hydrochloride 2%

Zinc acetate 0.1%

Purpose

Topical analgesic

Skin protectant

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
- 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

- avoid contact with the 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.

Directions

- do not use more than directed
- adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

cetyl alcohol, diazolidinyl urea, methylparaben, PEG-2 stearate, PEG-20 stearate, propylene glycol, propylparaben, purified water

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO EXTRA STRENGTH BENADRYL® ITCH STOPPING CREAM ACTIVE
INGREDIENTS

Itch Relief Cream

RELIEVES:

- Insect Bites, Minor Skin Irritations & Rashes Due to Poison Ivy, Poison Oak & Poison Sumac

TopCare® health

EXTRA STRENGTH

Anti-Itch Cream 2%

DIPHENHYDRAMINE HYDROCHLORIDE 2% & ZINC ACETATE 0.1%

Topical Analgesic & Skin Protectant

NET WT 1 OZ (28 g)

COMPARE TO EXTRA STRENGTH
BENADRYL® ITCH STOPPING
CREAM ACTIVE INGREDIENTS*

Itch Relief Cream

RELIEVES:

- Insect Bites, Minor Skin Irritations & Rashes Due to Poison Ivy, Poison Oak & Poison Sumac



NDC 36800-622-64

TopCare
health

EXTRA STRENGTH

Anti-Itch Cream 2%

DIPHENHYDRAMINE HYDROCHLORIDE 2% & ZINC ACETATE 0.1%

Topical Analgesic & Skin Protectant

NET WT 1 OZ (28 g)

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
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QUESTIONS?
1-888-423-0139
topcare@topco.com
www.topcarebrand.com



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information or
call 1-888-423-0139



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, the distributor of Extra Strength Benadryl® Itch Stopping Cream.



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CODE AREA

TopCare
health

Anti-Itch Cream 2%

Topical Analgesic & Skin Protectant

<p>Drug Facts</p> <p>Active ingredients Purpose</p> <p>Diphenhydramine hydrochloride 2%.....Topical analgesic</p> <p>Zinc acetate 0.1%.....Skin protectant</p>		<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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 <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves pain and itching associated with: <ul style="list-style-type: none"> ■ 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 		<p>Directions</p> <ul style="list-style-type: none"> ■ do not use more than directed ■ adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times daily ■ children under 2 years of age: ask a doctor 	
<p>Warnings</p> <p>For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ on large areas of the body ■ with any other product containing diphenhydramine, even one taken by mouth <p>Ask a doctor before use</p> <ul style="list-style-type: none"> ■ on chicken pox ■ on measles <p>When using this product ■ avoid contact with the eyes ▶</p>		<p>Other information</p> <ul style="list-style-type: none"> ■ store at 20°-25°C (68°-77°F) <p>Inactive ingredients cetyl alcohol, diazolidinyl urea, methylparaben, PEG-2 stearate, PEG-20 stearate, propylene glycol, propylparaben, purified water</p>	
<p>Questions or comments? 1-888-423-0139</p>			

CODE AREA

TOPCARE ANTI ITCH

diphenhydramine hydrochloride, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-622
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
PEG-2 STEARATE (UNII: 94YQ11Y95F)	
PEG-20 STEARATE (UNII: NBX892EA57)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-622-64	1 in 1 CARTON	04/08/2020	
1		28 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 not final	part348	04/08/2020	

Labeler - Topco Associates LLC (006935977)