

DIPHENHYDRAMINE HYDROCHLORIDE AND ZINC ACETATE- diphenhydramine hydrochloride and zinc acetate cream
STRATEGIC SOURCING SERVICES LLC

Diphenhydramine Hydrochloride and Zinc Acetate

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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
 - 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 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 often 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: ask a doctor

Other information

- to open: unscrew cap, use pointed end of cap to puncture seal.
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

cetyl alcohol, glyceryl stearate, glyceryl stearate/PEG-100 stearate, methylparaben, propylene glycol, propylparaben and purified water

Questions?

call **833-358-6431** Monday to Friday 9:00am to 7:00pm EST

Distributed by: McKesson Corp.,
via Strategic Sourcing Services LLC.
Memphis, TN 38141

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Foster & Thrive™

EXTRA STRENGTH

Anti-Itch Cream

Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%

TOPICAL ANALGESIC / SKIN PROTECTANT

NET WT 1 OZ (28.4 g)

NDC 70677-1213-1

Foster & Thrive™

EXTRA STRENGTH

Anti-Itch Cream

Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%
TOPICAL ANALGESIC / SKIN PROTECTANT

- Relieves pain and itch from insect bites, minor skin irritations and rashes due to poison ivy, poison oak and poison sumac

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

5242623
1023
34

Foster & Thrive™

EXTRA STRENGTH

Anti-Itch Cream

Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%
TOPICAL ANALGESIC / SKIN PROTECTANT

NET WT 1 OZ (28.4 g)

Foster & Thrive™
Anti-Itch Cream
Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%
TOPICAL ANALGESIC / SKIN PROTECTANT

T51
B50.3
ENG19.13



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NO COPY ON THIS FLAP FOR LOT # AND EXPIRY DATE PRINT

<p>Drug Facts</p> <p>Active ingredients Diphenhydramine hydrochloride 2%, Zinc acetate 0.1%, Topical analgesic Skin protectant</p> <p>Purpose • symptomatic relief 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.</p> <p>Directions • do not use more often 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: ask a doctor</p> <p>Other information • top part unscrew cap, unscrewed end of cap to puncture seal • store at 20° to 25°C (68° to 77°F) • see bottom of tube comp for lot number and expiration date</p> <p>Inactive ingredients cetylalcohol, glyceryl stearate, glyceryl stearate PEG-100 carbate, methylparaben, propylene glycol, propylparaben and purified water</p> <p>Questions? call 1-833-358-6431 Monday to Friday 9:00am to 7:00pm EST</p>	
<p>Warnings For external use only</p> <p>Do not use • on large areas of the body • with any other product containing diphenhydramine, even one taken by mouth</p> <p>Ask a doctor before use • on children • on men</p> <p>When using this product, avoid contact with eyes • condition worsens or does not improve within 7 days</p> <p>Stop use and ask a doctor if</p>	<p>Uses • temporarily relieves pain and itching associated with: • insect bites • sunburn • minor skin irritations • minor cuts • scrapes • rashes due to poison ivy, poison oak, and poison sumac • die the coating and weeping of poison ivy, poison oak, and poison sumac</p> <p>Warnings • poison sumac</p>

Foster & Thrive™
EXTRA STRENGTH
Anti-Itch Cream
Diphenhydramine Hydrochloride 2%
and Zinc Acetate 0.1%
TOPICAL ANALGESIC
SKIN PROTECTANT

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1213	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	20 mg in 1 g	
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)		ZINC ACETATE	1 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
CETYL ALCOHOL (UNII: 936JST6JCN)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PEG-100 STEARATE (UNII: YD01N1999R)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KOOR)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1213-1	1 in 1 CARTON	12/13/2023	02/28/2027
1		28.4 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		12/13/2023	02/28/2027

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(70677-1213)