

# **DIPHENHYDRAMINE HCL AND ZINC ACETATE- diphenhydramine hydrochloride, zinc acetate cream**

**Padagis Israel Pharmaceuticals 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.*

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## **Perrigo Diphenhydramine HCl & Zinc Acetate 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?**

**1-800-719-9260**

**Principal Display Panel**

Extra Strength Itch Relief Cream

Relieves Itches from Insect Bites and Skin Irritations

Compare to Extra Strength Benadryl® Cream active ingredients

Diphenhydramine HCl & Zinc Acetate

Extra Strength Itch Relief Cream

Topical Analgesic - Skin Protectant

NET WT 1 OZ (28 g)

NDC 45802-358-03

## Extra Strength Itch Relief Cream

✓ Relieves Itches from Insect Bites  
and Skin Irritations



If your doctor writes a prescription  
for this product, it may be covered by

- ✓ FSA or HSA Accounts
- ✓ Private Health Plans
- ✓ Medicaid/Medicare

Perrigo®

Compare to Extra Strength Benadryl® Cream  
active ingredients

NDC 45802-358-03

## Diphenhydramine HCl & Zinc Acetate

Extra Strength Itch Relief Cream

Topical Analgesic • Skin Protectant

NET WT 1 OZ (28 g)



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Distributed By  
**Perrigo®**  
Allergan, MI 49010  
www.perrigo.com  
: 62264 RT C3



When public and private health plans provide  
coverage for OTC pharmaceuticals, consumers  
get relief and drug formularies can reduce costs.  
At Perrigo, we call it ORx

NDC 45802-358-03  
Diphenhydramine HCl  
& Zinc Acetate

## Diphenhydramine HCl & Zinc Acetate Extra Strength Itch Relief Cream

### Drug Facts

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Zinc acetate 0.1%.....	Skin protectant

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### Drug Facts (continued)

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**DIPHENHYDRAMINE HCL AND ZINC ACETATE**

diphenhydramine hydrochloride, zinc acetate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45802-358
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PEG-2 STEARATE</b> (UNII: 94YQ11Y95F)	
<b>PEG-20 STEARATE</b> (UNII: NBX892EA57)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-358-03	1 in 1 CARTON	12/05/2005	
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	12/05/2005	

**Labeler** - Padagis Israel Pharmaceuticals Ltd (600093611)