

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

Padagis Israel Pharmaceuticals Ltd

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)

Padagis™

NDC 45802-358-03

Extra Strength Itch Relief Cream

- Relieves Itches from Insect Bites and Skin Irritations

OTC via Rx

If a prescription is written for this product it may be covered by your health plan.

NDC 45802-358-03

Compare to Extra Strength Benadryl® Cream active ingredients

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Extra Strength Itch Relief Cream

Topical Analgesic • Skin Protectant

NET WT 1 OZ (28g)



NDC 45802-358-03
Diphenhydramine HCl
& Zinc Acetate

CODE AREA



3 45802-358-03 5

Distributed By



Allegan, MI 49010
www.padagis.com

62264 RT C5

DIPHENHYDRAMINE HCL AND ZINC ACETATE

diphenhydramine hydrochloride, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-358
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-20 STEARATE (UNII: NBX892EA57)	
DIETHYLENE GLYCOL MONO- AND DIPALMITOSTEARATE (UNII: 94YQ11Y95F)	

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 Drug	M017	12/05/2005	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

