CVS EXTRA STRENGTH ITCH RELIEF - diphenhydramine hydrochloride and zinc acetate ointment
CVS Pharmacy

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.

DRUG FACTS

Active ingredient **Purpose**

Diphenhydramine hydrochloride 2%.....Topical Analgesic
Zinc acetate.....Skin protectant

Uses

- for the temporary relief of itching and pain 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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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 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, or symptoms persist for ore 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

adults and children 2 years and older, apply to affected area not more than 3 to 4 times daily, or as directed by a doctor

children under 2 years of age: consult a doctor

Other information

- store at 20 degrees - 25 degrees C (68 to 70 degrees F) - Lot No. and Exp. Date, see crimp of tube or see box

Inactive Ingredients

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

CVS EXTRA STRENGTH ITCH RELIEF

diphenhydramine hydrochloride and zinc acetate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-053

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 - UNII:J41CSQ7QDS)	ZINC ACETATE	12 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARETH-2 (UNII: V56DFE46J5)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARETH-100 (UNII: 4OH5W9UM87)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-053-03	1 in 1 CARTON		
1		28 g in 1 TUBE		
2	NDC:59779-053-11	1 in 1 CARTON		
2		14 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/13/2010	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 9/2010 CVS Pharmacy