

SAVVY ITCH STOPPING- diphenhydramine hydrochloride zinc acetate cream **Savvy Care and Cosmetics**

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.

ITCH STOPPING CREAM

Active Ingredient

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

Ask a doctor before use

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 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

- store at 20 to 25°C (68-77°F)
- do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

Inactive Ingredients

cetyl alcohol, diazolidinyl urea, methylparaben, propylene glycol monostearate 1000, propylene glycol, propylparaben, purified water

Package Label



Drug Facts

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Zinc acetate 0.1% Skin protectant

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Drug Facts (continued)

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seal under cap is broken, missing or if the tube tip is cut prior to opening

Inactive ingredients

cetyl alcohol, diazolidinyl urea, methylparaben, polyethylene glycol
monostearate 1000, propylene glycol, propylparaben,
purified water

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

Specialty Manufactured for DELTA BRANDS INC., Larchmont, NY 10538 www.deltabrands.com

ITEM NO: 10371 / MADE IN INDIA

10371/01(007)

SAVVY ITCH STOPPING

diphenhydramine hydrochloride zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83650-102
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 CATION	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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83650-102-01	35.4 g in 1 TUBE; Type 0: Not a Combination Product	09/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/22/2023	

Labeler - Savvy Care and Cosmetics (915039748)

Establishment

Name	Address	ID/FEI	Business Operations
Savvy Care and Cosmetics		915039748	manufacture(83650-102)