

DR. SHEFFIELD ANTI ITCH CREAM- anti itch cream cream
Sheffield Pharmaceuticals LLC

Sheffield Extra Strength Anti- Itch Cream

Drug Facts:

Active ingredients

Diphenhydramine hydrochloride 2%

Zinc Acetate 0.1%

Purpose

Topical analgesic

Skin protectant

Uses

For temporary relief from pain and itching associated with :

- insect bites
- minor burns
- sunburn
- minor skin irritations
- rashes due to poison ivy, poison oak, and poison sumac

Dries the oozing and weeping of poison

- ivy
- oak
- 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 the 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

- conditions worsen 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 this and all drugs out of the reach of children.

If swallowed get medical help or contact a Poison Control Center immediately.

Directions

- do not use more than directed
- adults and children 2 years of age and older; apply to affected areas not more than 3 to 4 times daily
- children under 2 years of age , consult a doctor

Other Information

- Store at controlled room temperature 20°-25°C (68° - 77°F)
- Close the cap tightly after use

Inactive ingredients

Cetyl Alcohol, Diazoldinyl Urea, Methylparaben, PEG 20 Sterate, Propylene Glycol, Propylparaben, Purified Water

Principal Display Panel 1.25 oz Carton

Sheffield Pharmaceuticals

NDC 11527-069-04

ANTI -ITCH cream

Topical analgesic & Skin Protectant

Made in the USA

NET WT. 1.25 oz (35g)



Principal Display Panel 1.25 oz Tube

Sheffield Pharmaceuticals

NDC 11527-069-04

2% Diphenhydramine Hydrochloride and 0.1% Zinc Acetate

ANTI-ITCH cream

Histamine blocker relieves itching from insect bites & skin irritations

Topical Analgesic & Skin Protectant

NET WT. 1.25oz (35g)



NDC 11527-069-04

Compare to the active ingredients in Benadryl® Extra Strength*

Extra Strength

Anti-Itch Cream

BAN-ITCH™ TOPICAL ANALGESIC & SKIN PROTECTANT

NET WT. 1.25 oz. (35g)



Active ingredients:

Diphenhydramine hydrochloride 2% Topical analgesic
Zinc acetate 0.1% Skin protectant

Uses: For the temporary relief from pain and itching associated with: • insect bites • minor burns • sunburn • minor skin irritations • rashes due to poison ivy, poison oak, and poison sumac. • Dries the oozing and weeping of poison: • ivy • oak • 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 this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately. **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: consult a doctor. **Other information:** • Store at controlled room temperature 20°- 25°C (68°- 77°F) • Close the cap tightly after use. **Questions?** 1-800-222-1087. *This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark BENADRYL®. Distributed by Sheffield Pharmaceuticals, 170 Broad Street, New London, CT 06320 www.sheffieldpharma.com Made in the USA OF U.S. & Imported Ingredients and Components

Purpose:

Topical analgesic
Skin protectant

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DR. SHEFFIELD ANTI ITCH CREAM

anti itch cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-069
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)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-20 STEARATE (UNII: NBX892EA57)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-069-04	1 in 1 CARTON	11/11/2008	
1		35 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	M016	11/11/2008	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(11527-069)

Revised: 10/2023

Sheffield Pharmaceuticals LLC