

WELLY CALM BALM- anti itch cream cream

Welly Health PBC

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 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, Citric Acid, Diazolldinyl Urea, Glyceryl Sterate, Methylparaben, Polyethylene Glycol Monosterate 1000, Propylene Glycol, Propylparaben, Sodium Citrate , Purified Water

Principal Display Panel .57 oz Tube

Welly First aid NDC 72663-069-59

Extra Strength ANTI -ITCH cream

2% Diphenhydramine HCL topical analgesic

0.1% Zinc Acetate skin protectant

NET WT 0.57 oz (16g)



EXTRA STRENGTH
ITCH RELIEF CREAM

NET WT 0.57 oz (16 g)

2% Diphenhydramine
Hydrochloride Topical Analgesic &
0.1% Zinc Acetate Skin Protectant

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Purpose

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
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(20°-25°C) **Distributed by: Welly Health PBC Minneapolis, MN 55402 1-833-BE-WELLY**

wellyTM FIRST AID

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Principal Display Panel -Can

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NET WT 0.57 oz (16g)

2- Tubes 1.14 oz (32g)

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FIRST AID

welly™

Calm Balm

EXTRA STRENGTH
ITCH RELIEF CREAM



COUNT
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2 TUBES – 0.57 oz (16 g)
TOTAL NET WT 1.14 OZ (32 g)

2% Diphenhydramine Hydrochloride Topical Analgesic
& 0.1% Zinc Acetate Skin Protectant

Recycle me!
Welly™ www.GetWelly.com
Products of USA with globally
sourced materials RK18SHE

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Minneapolis, MN 55402
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WELLY CALM BALM

anti itch cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72663-069
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 CATION	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

METHYL PARABEN (UNII: A2I8C7H9T)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLENE GLYCOL MONOSTEARATE (UNII: MZM1I680W0)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-069-50	2 in 1 CAN	02/09/2019	
1		16 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 final	part347	02/09/2019	

Labeler - Welly Health PBC (116766884)

Registrant - Welly Health PBC (116766884)

Establishment			
Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(72663-069)