

**DCH CALASPRAY ITCH RELIEF- pramoxine hcl 1%, zinc acetate 0.1% spray**  
**Derma Care Research Labs, LLC**

*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.*

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**DCH Calaspray Itch Relief Spray, Pramoxine HCl 1%, Zinc Acetate 0.1%**

Pramoxine HCl 2%, Zinc Acetate 0.1%

Topical Analgesic, Skin Protectant

For the temporary relief of pain and itching associated with insect bites, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, and rashes due to poison ivy, oak, and sumac. Dries the oozing and weeping of poison ivy, oak, and sumac.

**For external use only. Flammable--**Keep away from fire or flame. **Do not use on** deep or puncture wounds, animal bites, or serious burns. **When using this product** avoid contact with eyes. In case of contact with eyes, flush thoroughly with water. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120F. . **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days.

If swallowed, get medical help or contact a Poison Control Center right away.

Shake well before use. Adults and children 12 years of age and older, apply to the affected area not more than 3 to 4 times daily. Children under 12 years of age: ask a doctor. To apply to face, spray into palm of hand and gently apply.

Alcohol Denat., Camphor, Citric Acid, Ethylhexylglycerin, Fragrance, glycerin, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polysorbate 40, Propylene Glycol, Sodium Citrate, Water.



DCH LABS

### Drug Facts

#### Active ingredients

Pramoxine HCl 1%.....Topical Analgesic  
Zinc Acetate 0.1%.....Skin Protectant

#### Purpose

**Uses** For the temporary relief of pain and itching associated with  
• rashes due to poison ivy, oak and sumac • insect bites • minor skin irritations • minor cuts • dries the oozing and weeping of poison ivy, oak and sumac.

#### Warnings

**Flammable** - Keep away from fire or flame.

**For external use only.**

**Do not use** • deep or puncture wounds • animal bites • serious burns.

**When using this product** • avoid spraying in eyes • In case of contact with eyes, flush thoroughly with water. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.

**Stop use and ask a doctor if** • condition worsens • rash or irritation develops and lasts for more than 7 days or clear up and occur again within a few days.

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

**Directions** • adults and children 2 years or older: apply to affected area not more than 3 to 4 times daily • children under 2 years of age: ask a doctor • to apply to face, spray into palm of hand and gently apply.

#### Inactive ingredients

Alcohol  
Denat., Camphor, Citric Acid, Ethylhexylglycerin,  
Fragrance, Glycerin, Hydroxypropyl  
Methylcellulose, Phenoxyethanol, Polysorbate 40,  
Propylene Glycol, Sodium Citrate, Water.

\*This product is not manufactured or distributed by Bausch Health®, owner of the registered trademark Caladryl®



Manufactured by:  
DermaCare Research Labs, LLC  
440 Fentress Blvd., Daytona Beach, FL 32114



## CalaSpray Itch Relief

### Clear Skin Protectant

Pramoxine HCl 1.0%  
Zinc Acetate 0.10%

Fast Relief from Poison Ivy,  
Oak, Sumac, Insect Bites  
and Minor Scrapes and Cuts

•  
Quick Drying

•  
Sprays at Any Angle

\* Compare to active ingredients in Caladryl®  
Net Wt. 3 oz (85 g)

## DCH CALASPRAY ITCH RELIEF

pramoxine hcl 1%, zinc acetate 0.1% spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-013
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
<b>ZINC ACETATE</b> (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	0.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYSORBATE 40</b> (UNII: ST11B5A2X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-013-03	85 g in 1 CAN; Type 0: Not a Combination Product	02/18/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/18/2021	

**Labeler** - Derma Care Research Labs, LLC (116817470)

**Registrant** - Derma Care Research Labs, LLC (116817470)

### Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72839-013)

Revised: 6/2023

Derma Care Research Labs, LLC