

# **HEB CALACLEAR- zinc acetate and pramoxine hydrochloride lotion**

## **H E B**

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### **HEB Calaclear Lotion**

#### **Drug Facts**

##### **Active Ingredients**

Zinc Acetate 8%

Pramoxine HCl 1%

##### **Purpose**

Skin Protectant

External analgesic

##### **Uses**

Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other skin irritations.

##### **Warnings**

For external use only. Use only as directed.

When using this product. Avoid contact with eyes and mucous membranes.

Ask a doctor before using on children 2 years of age.

##### **Stop use and ask a doctor if**

condition worsens. Symptoms last for more than 7 days or clear up and occur again within a few days.

##### **Keep out of reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

##### **Directions**

Adults and children 2 yr. of age and older. Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for comfort.

Children under 2 yrs. of age. Consult a doctor before use.

### Inactive Ingredients

SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

### Other information

Store at room temperature 15-30C (59-86F)

### Label



<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Pramoxine HCl 1%.....	External analgesic
Zinc acetate 0.1%.....	Skin protectant
<b>Uses</b> Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac or other minor skin irritations.	
<b>Warnings:</b> ■ <b>For External use only.</b> Use only as directed	
■ <b>Avoid contact with eyes and mucous membranes</b>	
■ <b>Ask a doctor before using</b> on children under 2 yrs. of age	
<b>When using this product</b> ■ <b>Discontinue use</b> if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few days and consult a doctor.	
<b>Keep out of reach of children.</b> In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.	
<b>Directions</b>	
■ <b>Adults and children 2 yrs. and older:</b> Shake well before using. Wash the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth not more than 3 to 4 times daily as needed for comfort.	
■ <b>Children under 2 yrs. of age:</b> Consult a doctor.	
■ <b>Other information</b> ■ Store at room temperature 15° - 30°C (50° - 86°F)	
<b>Inactive ingredients</b> ■ SD alcohol 38B 2.5%, camphor, diazolidinyl urea, fragrances, glycerin, hydroxypropyl methylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben and purified water.	

**MADE WITH PRIDE AND CARE FOR H-E-B, SAN ANTONIO, TX 78204**  
 Questions or Comments? Call 1-800-662-3435

We believe the high quality of this H-E-B product makes it an outstanding value. We hope you'll agree. If not, we'll cheerfully refund your money. 0

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## HEB CALACLEAR

zinc acetate and pramoxine hydrochloride lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:37808-040

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-040-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/26/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	03/25/1998	

**Labeler** - H E B (007924756)

**Registrant** - Pharma Nobis, LLC (118564114)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(37808-040) , manufacture(37808-040) , pack(37808-040) , label(37808-040)