

HEB CALAGESIC- zinc acetate and pramoxine hydrochloride lotion

H E B

HEB Calagesic 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 Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

Other information

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

Label

H-E-B
Calagesic™
Lotion
 ANTI ITCH FORMULA
Fast Soothing Relief
 For use on poison ivy,
 poison oak, chicken pox
 & other minor skin ailments
6 FL OZ (177mL)

Drug Facts

Active ingredients	Purpose
Calamine 8%.....	Skin protectant
Pramoxine 1%.....	External analgesic

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

Warnings: For External Use Only. Use only as directed.
 ■ **Avoid contact with eyes and mucous membranes**
 ■ **Ask a doctor before using** on children under 2 yrs. of age

When using this product ■ **Discontinue use** 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.

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 yrs. and older:** 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.

Children under 2 yrs. of age: Consult a doctor.

■ **Other information** ■ Store at room temperature 15° - 30°C (59° - 85°F)

Inactive ingredients ■ 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 1104
 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 4 1220 66068 1

HEB CALAGESIC			
zinc acetate and pramoxine hydrochloride lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-968
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-968-96	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(37808-968) , manufacture(37808-968) , pack(37808-968) , label(37808-968)