

**HARRIS TEETTER CALAGESIC- zinc acetate and pramoxine hydrochloride lotion**  
**Harris Tetter, LLC.**

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**Harris Teeter 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 Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

### Other information

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

### Label

Compare to active ingredients in Caladryl® Clear™ Lotion\*

**Harris Teeter**®

**Calaclear**®  
**Lotion**

**Skin Protectant • Drying Agent**  
**External Analgesic**

Topical relief of minor irritations due to:  
Poison Ivy, Poison Oak, Poison Sumac  
and other minor skin irritations.

6 FL OZ (177 mL)

**Drug Facts**

Active ingredients	Purpose
Pramoxine HCl 1%.....	External analgesic
Zinc Acetate 0.1%.....	Skin protectant

**Uses**  
Dries the oozing and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison 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 years 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.

*Continued* ▶

This product is not manufactured or distributed by Pfizer, owner of the registered trademark \*Caladryl® Clear™ Lotion

**Drug Facts (CONTINUED)**

**Directions**

- Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for comfort.
- Children under 2 years of age: Consult a doctor before use.

**Other information**  
Store at room temperature 15-30°C (50-86°F)

**Inactive ingredients**  
SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water.

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MATTHEWS, NC 28105  
**your plus guarantee.**  
1-800-432-6111 or harristeeter.com

## HARRIS TEETTER CALAGESIC

zinc acetate and pramoxine hydrochloride lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:69256-400

<b>Route of Administration</b>	TOPICAL
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### 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:69256-400-96	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** - Harris Tetter, LLC. (048463103)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(69256-400) , manufacture(69256-400) , pack(69256-400) , label(69256-400)