

RUGBY CALDYPHEN CLEAR- pramoxine hydrochloride and zinc acetate lotion

Rugby Laboratories

Rugby CaldypHEN Clear Lotion

Pramoxine HCl 1%

Zinc Acetate 0.1%

External Analgesic

Skin Protectant

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

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.

Adults and children 2 yrs. 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.

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

In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.



pramoxine hydrochloride and zinc acetate lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1269
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
ALCOHOL (UNII: 3K9958V90M)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1269-58	177 mL in 1 CONTAINER; Type 0: Not a Combination Product	12/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	12/30/2019	

Labeler - Rugby Laboratories (079246066)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0536-1269) , label(0536-1269) , analysis(0536-1269) , pack(0536-1269)

Revised: 12/2023

Rugby Laboratories