DERMAGESIC- pramoxine hcl, zinc oxide, calamine cream
Llorens Pharmaceutical International Division

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.

Active Ingredients

Pramoxine HCl 1%

Zinc Oxide 0.4%

Calamine 0.4%

Purpose

Anestheric/Analgesic

Skin Protectant

Uses

- for temporary reilef of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor irritation
- dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Warnings

For external use only. Avoid contact with the eyes

- Not for Pediatric use
- Hypersensitivity to "caine" anesthetics

Do not use

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth.

Ask a doctor before use

- on chicken pox
- on measles

Stop use and ask a doctor if condition worsens or does not improve within 7 days

- symptoms persist for more than 7 days or clear up and occur again within a few days

KEEP OUT OF REACH OF CHILDREN

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

Directions

- Adults and children 2 years of age and older apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age ask a doctor
- Do not use more often than directed

Inactive Ingredients

Aloe Badbadensis Leaf juice (Aloe Vera), Avena Sativa (Oat) Kernal colloidal, cetyl stearyl alcohol, ceteareth-6, ceteareth-25, diazolidinyl urea, fragrance, menthol, methyl paraben, paraffinum liquidum, propylene glycol, propyl paraben, purified water, stearyl alcohol

Questions or Comments

1-866-595-5598

DERMAGESIC

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-202
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 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4 mg in 1 g
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	4 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE (UNII: V5VD430YW9)	
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARETH-6 (UNII: 2RJS3559D3)	
CETEARETH-25 (UNII: 8FA93U5T67)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-202-04	113 g in 1 JAR; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	04/01/2016	

Labeler - Llorens Pharmaceutical International Division (037342305)

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