

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

Dermagesic 202

Active Ingredients

Pramoxine HCl 1%

Zinc Oxide 0.4%

Calamine 0.4%

Purpose

Anesthetic/Analgesic

Skin Protectant

Uses

- for temporary relief 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, cetareth-6, cetareth-25, diazolidinyl urea, fragrance, menthol, methyl paraben, paraffinum liquidum, propylene glycol, propyl paraben, purified water, stearyl alcohol

Questions or Comments

1-866-595-5598

<p>Drug Facts</p> <p>Active Ingredients</p> <table border="0"> <tr> <td>Pramoxine HCl.....1%</td> <td>Anesthetic/Analgesic</td> </tr> <tr> <td>Zinc Oxide.....0.4%</td> <td>Skin Protectant</td> </tr> <tr> <td>Calamine.....0.4%</td> <td>Skin Protectant</td> </tr> </table> <p>Uses ■ for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor irritations ■ dries the oozing and weeping of poison ivy, poison oak and poison sumac.</p> <p>Warnings ■ For external use only. Avoid contact with the eyes. ■ Not for Pediatric use ■ Hypersensitivity to "calne" anesthetics</p> <p>Do not use ■ on large areas of the body ■ with any other product containing diphenhydramine, even one taken by mouth</p> <p>Ask a doctor before use ■ on chicken pox ■ on measles</p> <p>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.</p> <p>KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.</p>	Pramoxine HCl.....1%	Anesthetic/Analgesic	Zinc Oxide.....0.4%	Skin Protectant	Calamine.....0.4%	Skin Protectant	<p>NDC 54859-202-04</p> <h1>DERMAGESIC</h1> <p>CREAM</p> <p>SKIN PROTECTANT • ANESTHETIC For Soothing Relief of Itching Due To...</p> <p>• Chicken Pox • Insect Bites • Prickly Heat</p> <p>4 FL. OZ. (113 g) www.llorenpharm.com</p> <p>Manufactured for: LLOREN Lloren Pharmaceutical International Division Miami, FL 33147 www.llorenpharm.com</p>	<p>Drug Facts Continued</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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 <p>Inactive Ingredients: Aloe Barbadesis Leaf Juice (Aloe Vera), Avena Sativa (Oat) Kernel Colloidal, Cetyl stearyl alcohol, Cetareth-6, Cetareth-25, Diazolidinyl Urea, Fragrance, Menthol, Methyl Paraben, Paraffinum liquidum, Propylene Glycol, Propyl Paraben, Purified Water, Stearyl Alcohol</p> <p>Other Information ■ Store at room temperature 15°-30°C (59°-86° F). ■ Tamper evident. Do not use if there is evidence of tampering.</p> <p>Questions or Comments? 1-866-595-5598</p> <p>Rev. 11/15</p> <p>Lot # _____ Exp. Date: _____</p> <p style="text-align: right;">NON-VARNISH</p>
Pramoxine HCl.....1%	Anesthetic/Analgesic							
Zinc Oxide.....0.4%	Skin Protectant							
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DERMAGESIC

pramoxine hcl, zinc oxide, calamine cream

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: 5P8D0Z 74RG)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETARETH-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: 059QF0KOOR)	
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 Drug	M017	04/01/2016		

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2025

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