DERMAGESIC- pramoxine hcl, zinc oxide, calamine liquid
Llorens Pharmaceuticals 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 **Purpose**

Pramozine HCl .... 1% ..... Anesthetic/Analgesic

Zinc Oxide .....0.4% ..... Skin Protectant

Calamine .....0.4% ..... Skin Protectant

Purpose

Anesthetic/Analgesic

Skin Protectant

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.

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

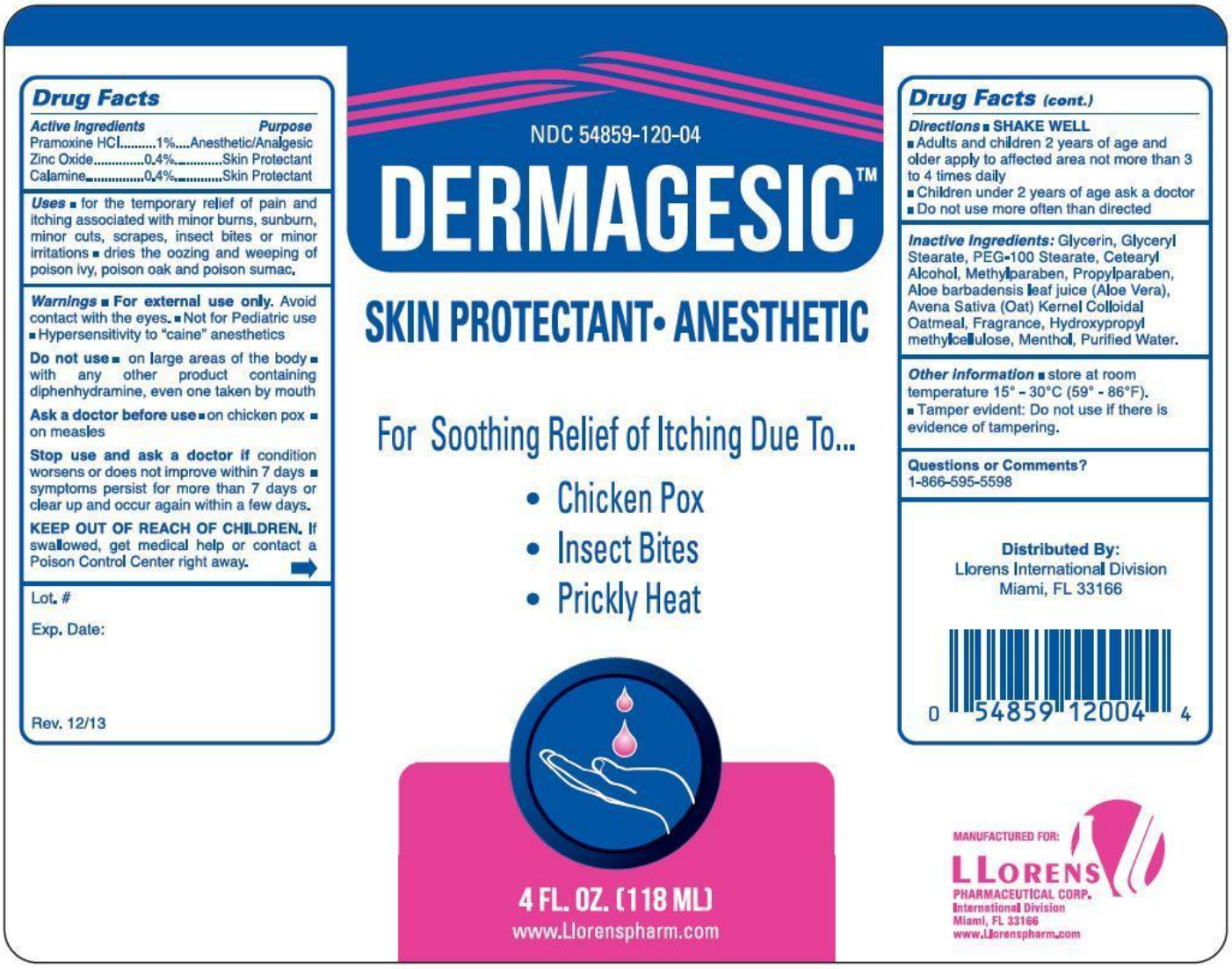
KEEP OUT OF REACH OF CHILDREN If swallowed, get medical help or contact a Poison Control Center right away.

Directions SHAKE WELL

- 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: Glycerin, glyceryl stearate, PEG-100 Stearate, cetearyl alcohol, methylparaben, propylparaben, aloe barbadensis leaf juic (aloe vera), avena sativa (oat) kernel colloidal oatmeal, fregrance, hydroxypropyl methylcellulose, menthol, purified water

Questions: 1-866-595-5598



DERMAGESIC

pramoxine hcl, zinc oxide, calamine liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 mg in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.4 mg in 100 mL
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	0.4 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-120-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	01/01/2014	

Labeler - Llorens Pharmaceuticals International Division (037342305)

Revised: 6/2014 Llorens Pharmaceuticals International Division