

**CALAMINE- calamine, pramoxine hcl lotion**  
**United Natural Foods, Inc. dba UNFI**

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**Equaline 336.003/336AG**  
**Medicated Calamine Lotion**

**Active ingredients**

Calamine 8%

Pramoxine HCl 1%

**Purpose**

Skin protectant

External analgesic

**Use**

- for the temporary relief of pain and itching associated with minor skin irritations and rashes due to poison ivy, poison oak, or poison sumac
- dries the oozing and weeping of poison:
  - ivy
  - oak
  - sumac

**Warnings**

**For external use only**

**When using this product**

- do not get into eyes

**Stop use and ask a doctor**

- condition worsens
- symptoms last 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
- before applying was affected are of skin

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 - do not use, ask a doctor

### **Other information**

store at room temperature (59°-77°F)

### **Inactive ingredients**

alcohol, benzyl alcohol, camphor, fragrance, hydroxypropyl methylcellulose, Lavandula angustifolia (lavender) oil, phenoxyethanol, polysorbate 80, propylene glycol, Rosmarinus officinalis (rosemary) leaf oil, water, xanthan gum

### **Disclaimer**

\*This product is not manufactured or distributed by Bausch Health US, LLA, distributor of Caladryl Lotion Calamine Plus Itch Reliever.

### **ADVERSE REACTION**

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

855-423-2630

### **Principal display panel**

Compare to Caladryl<sup>®</sup> Lotion active ingredient\*

NDC 41163-536-30

EQUALINE<sup>®</sup>

medicated calamine lotion

external analgesic

skin protectant

drying action plus itch relief

6 FL OZ (177 mL)

**EQUALINE®**compare to  
**Caladryl® Lotion**  
active ingredients\*  
NDC 41163-534-30**medicated  
calamine  
lotion**external analgesic  
skin protectantdrying action  
plus itch relief**6 FL OZ (177mL)****Drug Facts****Active ingredients**Calamine 8%,  
Pramoxine HCl 1%,**Purpose**Skin protectant  
External analgesic**Uses**

- for the temporary relief of pain and itching associated with minor skin irritations and rashes due to poison ivy, poison oak, or poison sumac
- dries the oozing and weeping of poison: ivy oak sumac

**Warnings****For external use only**

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**Directions**

shake well before applying wash affected area of skin

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

do not use, ask a doctor

**Other information** store at room temperature (59°-77° F)**Inactive ingredients** alcohol, benzyl alcohol, camphor, fragrance, hydroxypropyl methylcellulose, Lavandula angustifolia (lavender) oil, phenylethanol, polysorbate 80, propylene glycol, Rosmarinus officinalis (rosemary) leaf oil, water, xanthan gum\*This product is not manufactured or distributed by Bausch Health US, LLC,  
distributor of Caladryl Lotion Calamine Plus Itch Reliever.**DISTRIBUTED BY UNFI**  
**PROVIDENCE, RI 02908 USA**  
**855-423-2630**

L00026486C

**CALAMINE**

calamine, pramoxine hcl lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-536
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	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>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-536-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2009	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	05/21/2009	

**Labeler** - United Natural Foods, Inc. dba UNFI (943556183)

**Registrant** - Nice-Pak Products, LLC (119091520)

## Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(41163-536)

Revised: 2/2026

United Natural Foods, Inc. dba UNFI