

**FIRST DEGREE MAXIMUM STRENGTH BURN- pramoxine hydrochloride cream**  
**Welmedix LLC**

*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.*

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**First° Degree® Maximum Strength Burn Cream**

***Drug Facts***

**Active ingredient**

Pramoxine HCL 1%

**Purpose**

External analgesic

**Uses**

For the temporary relief of pain and itching associated with:

- minor burns
- insect bites
- sunburns
- minor cuts
- scrapes
- minor skin irritations

**Warnings**

**For external use only. Avoid contact with the eyes**

**Do not use**

- if you are allergic to any of the ingredients
- over large areas of the body

**Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 1 week, or clear up and occur again within a few days
- rash or other allergic reaction develops

**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:
  - clean the affected area
  - apply to affected area not more than 3 to 4 times daily
  - may be covered with a sterile bandage
- children under 2 years of age: ask a doctor

**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients**

butyrospermum parkii (shea butter), C18-22 hydroxyalkyl hydroxypropyl guar, calendula officinalis extract, cantharis vesicatoria extract, echinacea angustifolia extract, ethyl alcohol, hydrogenated polydecene, isopropyl myristate, lanolin, lanolin alcohol, petrolatum, phenoxyethanol, water, sodium hydroxide, sodium polyacryloyldimethyl taurate, trideceth-10

**Questions or Comments?**

1-888-565-2876

Monday through Friday, 9am-5pm EST

Distributed by:

**Welmedix Consumer Healthcare**

Princeton, NJ 08540

**PRINCIPAL DISPLAY PANEL - 21 g Tube Box**

**NEW &  
IMPROVED!**

**First°Degree®**

**MAXIMUM STRENGTH**

**BURN CREAM**

**PRAMOXINE HCL 1% PAIN RELIEVING CREAM**

**FAST RELIEF FOR  
PAIN + ITCH**

- GREAT FOR  
**MINOR  
BURNS  
BUG  
BITES**
- HELPS REDUCE THE APPEARANCE OF SCARS
- ENRICHED WITH NOURISHING BOTANICALS

1 Tube

Net Wt 3/4 oz (21 g)



## FIRST DEGREE MAXIMUM STRENGTH BURN

pramoxine hydrochloride cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24330-130
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

## Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ)	
LYTTA VESICATORIA (UNII: 3Q034RO3BT)	
GUAR GUM (UNII: E891I637KE)	
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)	
ALCOHOL (UNII: 3K9958V90M)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM TAURATE (UNII: Y7LJA74T0N)	
TRIDECETH-10 (UNII: G624N6MSBA)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24330-130-02	1 in 1 BOX	03/09/2017	
1		21 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	03/09/2017	

**Labeler** - Welmedix LLC (830387812)