LIDOCAINE PLUS MAXIMUM STRENGTH PAIN RELIEVING CREAM- lidocaine hydrochloride cream
Prime Enterprises Inc.

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.

Lidocaine Plus Maximum Strength Pain Relieving Cream

Active Ingredients

Lidocaine Hydrochloride 4%

Purpose

Pain Relieving Cream

Indications (Uses)

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.

For external use only.

Avoid contact with the eyes.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

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**: Consult a doctor.
- **Always tighten cap firmly after each use**

Aloe Barbadensis Leaf Juice, Benzophenone-4, Blue 1, Carbomer, Diazolidinyl Urea, Disodium EDTA, DMDM Hydantoin, Fragrance, Menthol, Methylparaben, Polysorbate 20, Propylene Glycol, SD Alcohol 40-B, Triethanolamine, Water, Yellow 5

Other Information

Questions or Comments?

Call 1-888-263-9808

Lidocaine Plus Maximum Strength Pain Relieving Cream

LIDOCAINE PLUS MAXIMUM STRENGTH PAIN RELIEVING CREAM

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	39.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
LAURETH-7 (UNII: Z95S6G8201)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	green	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58443-0123-3	118 mL in 1 TUBE; Type 0: Not a Combination Product	03/02/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/02/2007	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0123) , manufacture(58443-0123) , label(58443-0123) , analysis(58443-0123)

Revised: 7/2020 Prime Enterprises Inc.