SUNTONE AFTER SUN BURN RELIEF GEL WITH LIDOCAINE- lidocaine hydrochloride gel
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.

Suntone After Sun Burn Relief Gel with Lidocaine

Active Ingredients

Lidocaine Hydrochloride (0.72%)

Purpose

External Analgesic

Uses

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or 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 contact a physician.

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

Keep out of reach of children. If product is 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

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

Questions or Comments?

Biocycle Laboratories, Inc.

16363 NW 49 Avenue, Miami, FL 33014

Suntone After Sun Burn Relief with Lidocaine

Suntone After Sun Burn Relief Gel is formulated with Lidocaine and Aloe Vera to soothe, cool, and moisturize skin.

Drug Facts

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16363 NW 49 Avenue, Miami, FL 33014

Distributed by:
Biocycle Laboratories, Inc.
Miami, FL 33014

MADE IN USA

0 87524 97008 8

SUNTONE AFTER SUN BURN RELIEF GEL WITH LIDOCAINE

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0125

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	7.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0125-6	470 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/07/2011	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0125) , manufacture(58443-0125) , label(58443-0125)

Revised: 6/2020

Prime Enterprises Inc.