


SOLMATE BURN RELIEF GEL- 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.

PRINCIPAL DISPLAY PANEL - 591 mL Bottle Label

BIG LOTS! \$4
120 07 007
215 810244333 4 035

SOLMATE
Love the Sun



BURN RELIEF GEL
External Analgesic
with Lidocaine

*Contains
Skin Moisturizing
Aloe Vera*

20 FL OZ (591mL)

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

Drug Facts	
Active Ingredient 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.	
Warnings 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 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	
Inactive ingredients 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	

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

MADE IN USA

0 87524 96037 19

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SOLMATE BURN RELIEF GEL			
lidocaine hydrochloride gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0145

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.057 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZOPHENONE (UNII: 701M4TTV9O)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0145-7	591 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2015	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0145) , pack(58443-0145) , manufacture(58443-0145) , analysis(58443-0145)

Revised: 1/2015

Prime Enterprises, Inc.