PANAMA JACK BURN RELIEF GEL WITH LIDOCAINE- lidocaine hydrochloride gel
Prime Enterprises Inc.

Panama Jack Burn Relief with Lidocaine

Active Ingredients

Lidocaine Hydrochloride (0.72%)

Purpose

Topical Analgesic

Uses

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

For external use only.

When using this product
- Avoid contact with the eyes. If contact occurs, rinse thoroughly with water.

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

Stop use and contact a physician
- If irritation occurs.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

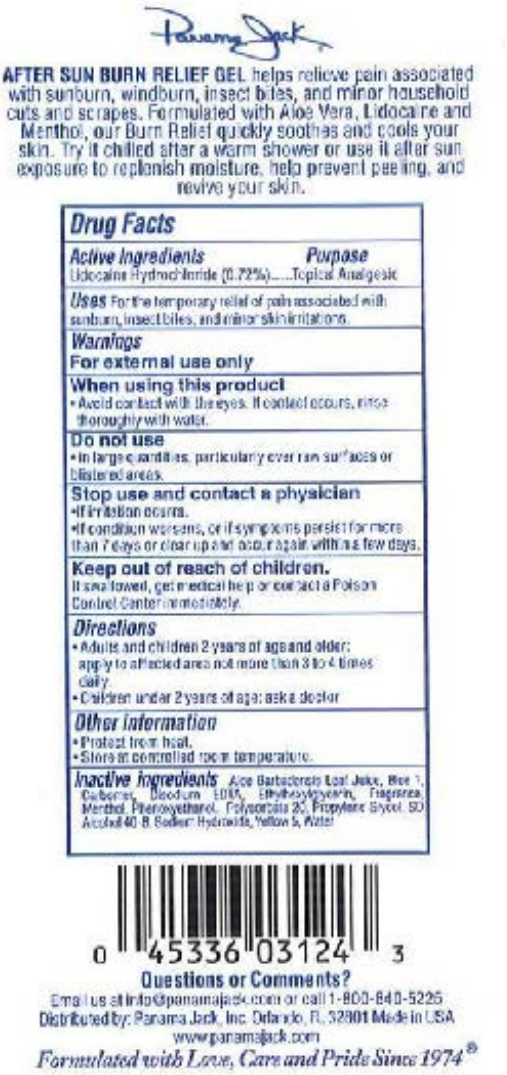
If swallowed, get medical help or contact a Poison Control Center immediately.

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

Other Information
- Protect from heat,
- Store at controlled room temperature.

Aloe Barbadensis Leaf Juice, Blue 1, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Menthol, Phenoxyethanol, Polysorbate 20, Propylene Glycol, SD Alcohol 40-B, Sodium Hydroxide, Yellow 5, Water

Panama Jack Burn Relief with Lidocaine



PANAMA JACK BURN RELIEF GEL WITH LIDOCAINE

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0648
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL (UNII: L7T10EIP3A)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
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:58443-0648-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/19/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/19/2015	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0648) , manufacture(58443-0648) , label(58443-0648) , analysis(58443-0648)

Revised: 5/2024

Prime Enterprises Inc.