PANAMA JACK BURN RELIEF GEL WITH LIDOCAINE- lidocaine 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.

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

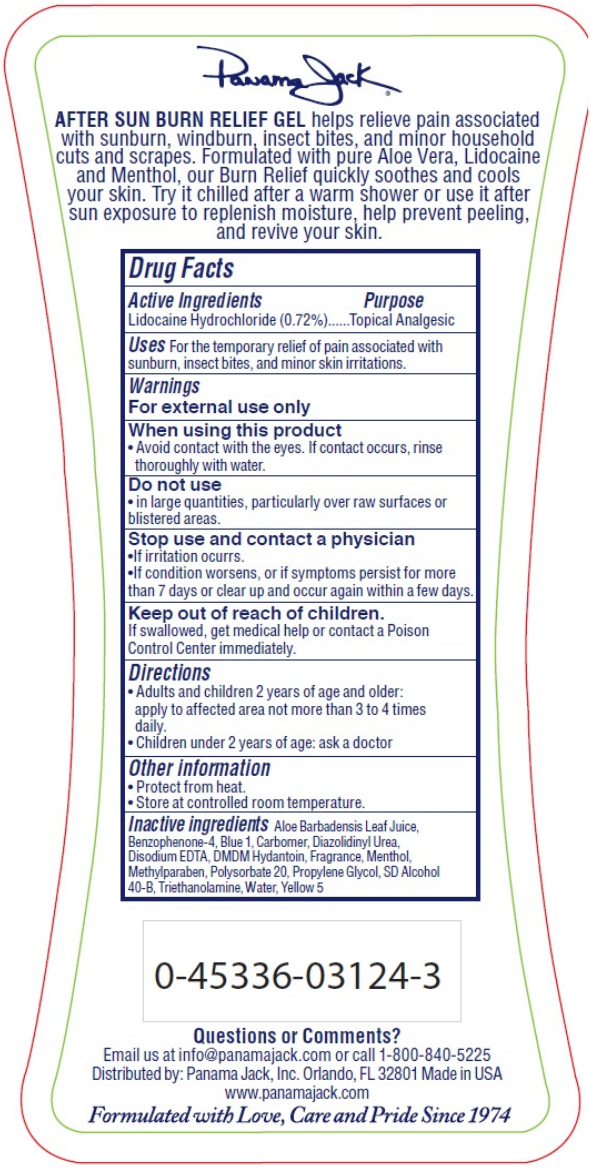
- Protect from heat,
- Store at controlled room temperature.

Aloe Barbadensis Leaf Juice, 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?

Email us at info@panamajack.com or call 1-800-840-5225

Panama Jack Burn Relief with Lidocaine



PANAMA JACK BURN RELIEF GEL WITH LIDOCAINE

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0204
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 HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (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:58443-0204-4	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 final	part346	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(58443-0204) , manufacture(58443-0204) , label(58443-0204)

Revised: 1/2020 Prime Enterprises Inc.