

PANAMA JACK 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.

Panama Jack Burn Relief Gel with Aloe Vera and 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.

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

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.

Inactive Ingredients

Aloe Barbadosis 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 Topical Analgesic Gel



Panama Jack

AFTER SUN BURN RELIEF GEL helps relieve pain associated with sunburn, windburn, insect bites, and minor household cuts and scrapes. Formulated with Aloe Vera, Lidocaine and Menthol, our Burn Relief quickly soothes and cools your skin. Try it chilled after a warm shower or use it after sun exposure to replenish moisture, help prevent peeling, and revive your skin.

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Questions or Comments?

Email us at info@panamajack.com or call 1-800-840-5225
Distributed by: Panama Jack, Inc. Orlando, FL 32801 Made in USA
www.panamajack.com

Formulated with Love, Care and Pride Since 1974®

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0261
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	7.128 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0K00R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0261-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/25/2018	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0261) , manufacture(58443-0261) , label(58443-0261) , analysis(58443-0261)

Revised: 1/2020

Prime Enterprises Inc.