AUSTRALIAN GOLD ALOE 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.

Australian Gold Lidocaine ALOE GEL

Active ingredients

Lidocaine Hydrochloride(0.5 %)

Purpose

External Analgesic

Indications

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 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 doctor

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

Keep out of reach of children. if product is swallowed, get medical help or contact a poison control center right away.

For external use only.

Avoid contact with eyes.

If conditions worsens, or is 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 doctor.

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 afftected area not more than 3 to 4 times daily.
- Children under 2 years of age:

  consult a doctor.

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Blue 1, Caprylyl Glycol, Carbomer, Citrus Limon (Lemon) Peel Extract, Glycerin, Glyceryl Acrylate/Acrylic Acid Copolymer, Hexylene Glycol, Mentha Viridis (Spearmint) Leaf Oil, Panthenol, PEG-60 Lanolin, Phenoxyethanol, Pollen Extract, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Symphytum Officinale (Comfrey) Leaf Extract, Tilia Cordata Flower Extract, Tocopheryl Acetate, Water

Questions or Comments?

Call toll free 1-855-LIV-GOLD (546-4653)

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

AUSTRALIAN GOLD ALOE GEL WITH LIDOCAINE

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0327
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5.05 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALLANTOIN (UNII: 344S277G0Z)	
SCOTCH SPEARMINT OIL (UNII: I5T0098W81)	
PEG-60 LANOLIN (UNII: K2OI1D27ET)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
BEE POLLEN (UNII: 3729L8MA2C)	
COMFREY LEAF (UNII: DG4F8T839X)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
ALPHA-TOCOPHERYLQUINONE (UNII: ZO763K43XR)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 1342 (UNII: 809Y72KV36)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58443-0327-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/16/2015	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0327) , pack(58443-0327) , manufacture(58443-0327) , analysis(58443-0327)

Revised: 5/2020 Prime Enterprises, Inc.