BOTANIKA LIFE SOOTHING PAIN SERUM- licocaine hydrochloride, menthol liquid
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.

Botanika Life Super Soothing Pain Serum

Active Ingredients

Lidocaine Hydrochloride 4%

Menthol 1%

Purpose

Topical 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

Do not use

in large quantities, particularly over raw surfaces or blistered areas.

When using this product

avoid contact with the eyes.

Use only as directed.

Stop use and ask a doctor

if condition worsens, or if symptoms persist more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding,

ask a health professional before use.

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: Consult a doctor.

Inactive ingredients

Aloe Barbadensis Leaf Juice, Arnica Montana Flower Extract, Boswellia Serrata Extract, Cannabidiol, Dimethyl Sulfone, Glycerin, Polyacrylate-13, Polyisobutene, Polysorbate 20, SD Alcohol 40-B, Tocopheryl Acetate, Water

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Drug Facts

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BOTANIKA LIFE SOOTHING PAIN SERUM

licocaine hydrochloride, menthol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0391
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	38.44 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	9.61 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	white (White to Off-White)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0391-3	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/19/2020	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0391) , label(58443-0391) , analysis(58443-0391) , pack(58443-0391)

Revised: 1/2021 Prime Enterprises, Inc.