NATUREPLEX LIDOCAINE 4%- lidocaine cream Natureplex LLC

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.

Natureplex™ Lidocaine 4% Topical

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

Topical analgesic

Use

for the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations

Warnings

For external use only.

Avoid contact with eyes.

Not for prolonged use.

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

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days
- rash or irritation develops, persists, or increases

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

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

Other information

store at 15 to 30°C (59 to 86°F)

■ Tamper Evident: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, arginine, benzophenone-4, caprylyl glycol, cetyl alcohol, dimethyl sulfoxide, hexylene glycol, melaleuca alternifolia (tea tree) leaf oil, phenoxyethanol, potassium sorbate, purified water, simmondsia chinensis (jojoba) seed oil, sodium polyacrylate, stearic acid

Questions or comments?
866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Natureplex ™

* Compare active ingredients to Gold Bond® with 4% Lidocaine

Lidocaine 4%

Pain & Itch Relief Cream

NET WT. 1.0 Oz.(28g)



lidocaine cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67234-067

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987) Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)

Inactive Ingredients				
Ingredient Name	Strength			
Aloe Vera Leaf (UNII: ZY81Z83H0X)				
SULISOBENZONE (UNII: 1W6L629B4K)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
Cetyl Alcohol (UNII: 936JST6JCN)				
Dimethyl Sulfoxide (UNII: YOW8V9698H)				
Hexylene Glycol (UNII: KEH0A3F75J)				
TEA TREE OIL (UNII: VIF565UC2G)				
Phenoxyethanol (UNII: HIE492ZZ3T)				
Potassium Sorbate (UNII: 1VPU26JZZ4)				
WATER (UNII: 059QF0KO0R)				
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)				
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)				
Stearic Acid (UNII: 4ELV7Z65AP)				
Arginine (UNII: 94ZLA3W45F)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:67234-067- 01	1 in 1 CARTON	03/15/2017				
1		28 g in 1 TUBE; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333B	03/15/2017		

Labeler - Natureplex LLC (062808196)

Establishment						
Name	Address	ID/FEI	Business Operations			
Natureplex LLC		062808196	MANUFACTURE(67234-067)			

Revised: 5/2021 Natureplex LLC