BURNX PAIN RELIEVING BURN- lidocaine hydrochloride gel
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.

BurnX™
PAIN RELIEVING BURN GEL

Drug Facts

Active Ingredient

Lidocaine hydrochloride 2.5%

Purpose

Topical analgesic

Use

for the temporary relief of pain associated with minor burns, sunburn, 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 the 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

Carbomer, disodium EDTA, glycerin, melaleuca alternifolia (tea tree) leaf oil, octoxynol-9, propylene glycol (and) diazolidinyl urea (and) methylparaben (and) propylparaben, purified water, triethanolamine

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Natureplex™

PAIN RELIEVING BURN GEL
NDC 67234-037-01

BurnX™
LIDOCAINE HCL 2.5%
Topical Analgesic

For Burns and Sunburns

NET WT. 1 Oz.(28g)

BURNX PAIN RELIEVING BURN

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67234-037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.025 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TEA TREE OIL (UNII: VIF565UC2G)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67234-037-01	1 in 1 CARTON	04/10/2010	
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 NOT FINAL	part348	04/10/2010	

Labeler - Natureplex, LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-037)