

BIO-SCRIPTIVES LIDUM - lidocaine cream

BioChemics, 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.

Drug Facts

Active Ingredient

Lidocaine 5%

Purpose

Topical Anesthetic

Uses

- rapid onset
- temporary relief of pain and itching due to
- minor burns
- skin irritations
- scrapes
- cuts
- sunburn
- insect bites

Warnings

For external use only.

Do Not Use

- in or near eyes
- in large quantities, particularly over raw surfaces or blistered areas

Stop use if

- allergic reaction occurs
- condition worsens or does not improve within 7 days

Keep out of the reach of children.

Directions

- adults and children 2 years and up apply externally to affected areas 3-4 times a day.

Inactive Ingredients

Aloe Vera Juice, Water, Cholesterol, Isopropyl Myristate, Aqua and Caprylic Capric Triglyceride and Propylene Glycol and Hydrogenated Phosphatidylcholine, Glyceryl Stearate and PEG-100 Stearate, Arginine HCl, Ethyl Oleate, Propylene Glycol, dAlpha-Tocopheryl Polyethylene Glycol-1000 Succinate, Cetyl Alcohol, Triethanolamine, Xanthan Gum, Vitamin E, Allantoin, Aloe Vera Powder, Methylisothiazolinone, Methyl Nicotinate

Labels

BIO-SCRIPTIVES®

Lidum™
(Lidocaine 5%)

Topical Anesthetic Cream

Clinically Tested
Rapid Onset

Derma-Release® Delivery
System

Net Wt 2 oz (56 g)

OPEN

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Drug Facts (continued)

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Inactive Ingredients

Aloe Vera Juice, Water, Cholesterol,
Isopropyl Myristate, Aqua & Caprylic/
Capric Triglyceride & Propylene
Glycol & Hydrogenated
Phosphatidylcholine, Glyceryl
Stearate & PEG-100 Stearate,
Arginine HCl, Ethyl Oleate, Propylene
Glycol, d-Alpha-Tocopheryl
Polyethylene Glycol-1000 Succinate,
Cetyl Alcohol, Triethanolamine,

Xanthan Gum, Vitamin E, Allantoin,
Aloe Vera Powder,
Methylisothiazolinone, Methyl
Nicotinate

Distributed by Bio-Scriptives
99 Rosewood Drive #260
Danvers, MA 01923 | 978-750-0090

BIO-SCRIPTIVES LIDUM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60608-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride	2.8 g in 56 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
TOCOPHERSOLAN (UNII: O03S90U1F2)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALLANTOIN (UNII: 344S277G0Z)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYL NICOTINATE (UNII: 7B1AVU9DJN)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60608-011-00	56 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/23/2010	

Labeler - BioChemics, Inc (802946426)