

BIO-SCRIPTIVES LIDUM HEMORROIDAL (ANORECTAL)- lidocaine cream

Bio-Scriptives, 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.

Bio-Scriptives Lidum (Lidocaine 5%) Hemorrhoidal (Anorectal) Cream

Active Ingredient

Lidocaine 5%

Purpose

Local Anesthetic

Uses

- For the temporary relief of local discomfort associated with anorectal disorders
- For the temporary relief of pain, soreness, and burning.

Warnings

For external use only.

When using this product ■ do not exceed the recommended daily dosage unless directed by a doctor.

- do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and consult a doctor if:

- condition worsens or does not improve within 7 days
- bleeding occurs
- allergic reaction occurs
- redness, irritation, swelling, pain or other symptoms develop or increase

Keep out of reach of children.

Directions

■ Children under 12 years of age: consult a doctor. ■ Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Apply externally to the affected area up to 6 times daily.

Inactive Ingredients

Aloe, Water, Cholesterol, Isopropyl Myristate, Aqua, Caprylic/Capric Triglyceride, Propylene Glycol, Hydrogenated Phosphatidylcholine, Glyceryl Stearate, PEG-100 Stearate, Arginine HCl, Ethyl Oleate, Propylene Glycol, Tocophersolan, Cetyl Alcohol, Triethanolamine, Xanthan Gum, Tocopherol, Allantoin, Aloe Barbadosensis Leaf, Methylisothiazolinone, Methyl Nicotinate

Package and Lidum Images

BIO SCRIPTIVES[®]
Lidum[®]
(Lidocaine 5%)

Hemorrhoidal (Anorectal) Cream

Derma-Release[®] Technology

Net Wt 2 oz (56 g)

Drug Facts

Active Ingredient	Purpose
Lidocaine 5%	Local Anesthetic

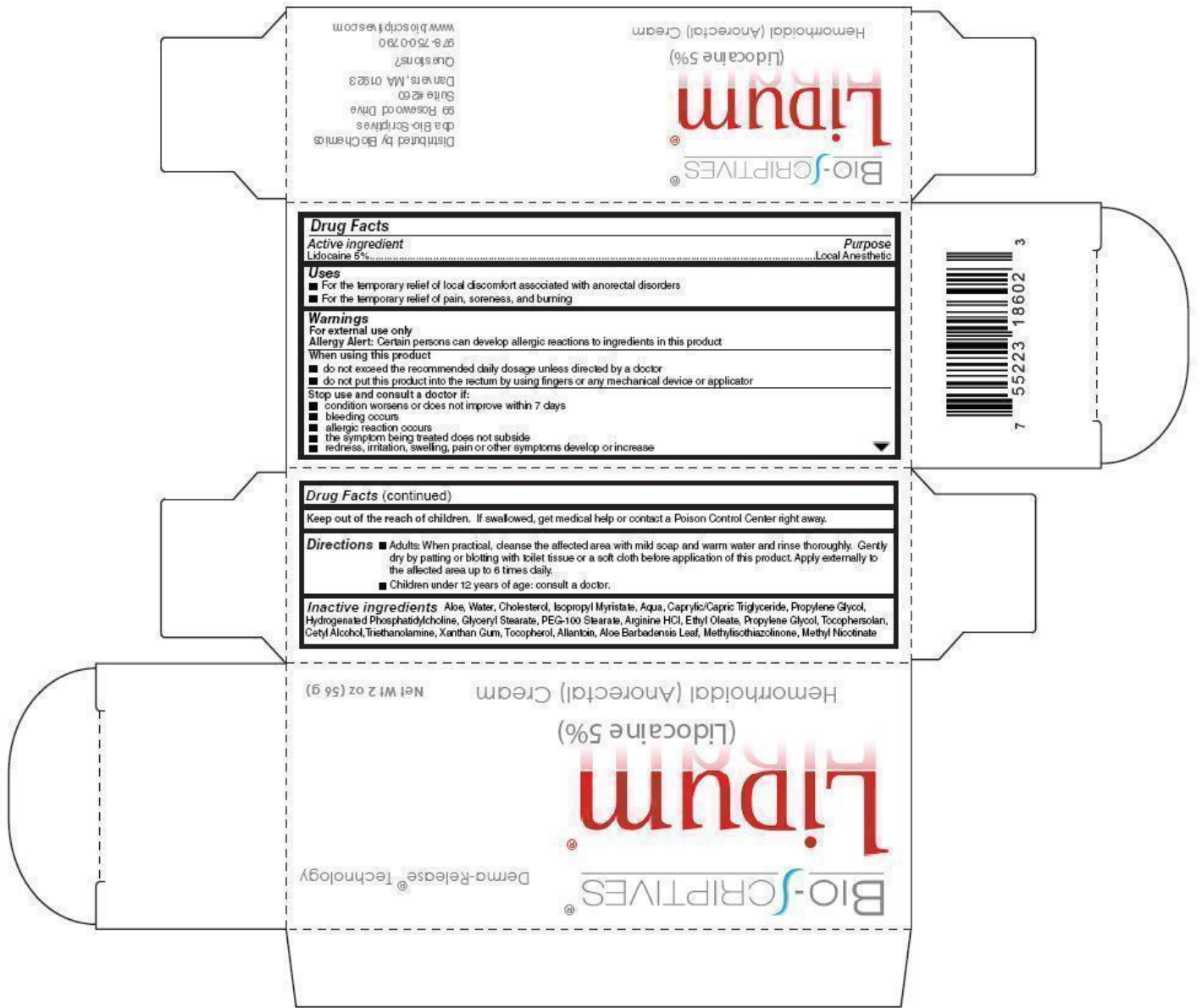
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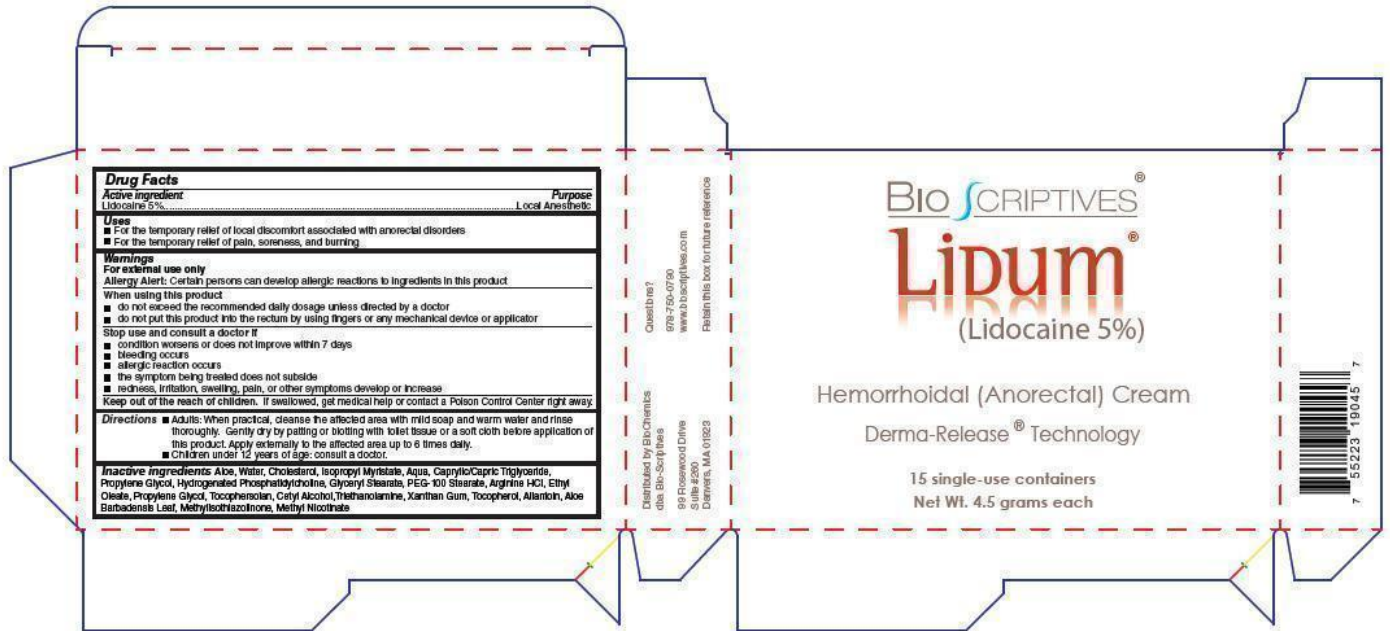


Lidum[®]

(Lidocaine 5%)

Net Wt. 4.5 grams

+



BIO-SCRIPTIVES LIDUM HEMORROIDAL (ANORECTAL)

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60608-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHERSOLAN (UNII: O03S90U1F2)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	

XANTHAN GUM (UNII: TTV12P4NEE)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALLANTOIN (UNII: 344S277G0Z)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYL NICOTINATE (UNII: 7B1AVU9DJN)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60608-016-01	1 in 1 BOX		
1	NDC:60608-016-00	56 g in 1 TUBE		
2	NDC:60608-016-03	15 in 1 BOX		
2	NDC:60608-016-02	4.5 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/04/2012	

Labeler - Bio-Scriptives, Inc. (802946426)

Establishment			
Name	Address	ID/FEI	Business Operations
Coastal Products Company		782445688	manufacture(60608-016)

Revised: 3/2012

Bio-Scriptives, Inc.