

**LIPOCAINE 5- lidocaine 5% cream**  
**ESBA LABORATORIES INC.**

-----  
**LIPOCAINE 5**

**Active ingredient:**

Lidocaine 5%

**Purpose**

Topical Anesthetic

**Use**

For temporary relief of pain and itching due to anorectal disorders.

**Warnings**

For external use only.

**When using this product:**

- avoid contact with eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas
- do not put in rectum
- do not exceed recommended dosage unless directed by a doctor.

**Stop use and ask a doctor if:**

- allergic reaction occurs
- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase.

**Keep out of the reach of children:**

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Directions:**

- When practical, clean area with mild soap and warm water and rinse thoroughly
- Gently dry by patting or blotting with toilet tissue or soft cloth before applying
- Adults and children 12 years old and older: Apply externally to the affected area up to 6 times a day
- Children under 12 years of age: consult a doctor.

**Other information:**

- Store at room temperature 20-25oC (68-77oF).
- Child-Resistant Cap: push down and turn to open
- Available in 1 Oz (30 g) and 4 Oz (113 g) tubes

**Inactive ingredients:**

Allantoin, Aloe Barbadosis Leaf Extract, Beta-Sitosterol, Caprylhydroxamic Acid, Cetyl Alcohol, Cetyl Palmitate, Glycerin, Glyceryl Caprylate, Isostearyl Alcohol, Lecithin, Purified Water, Sucrose Distearate, Sucrose Stearate , Tocopheryl Acetate, Triethylcitrate, Xanthan Gum.

**Questions**

Call toll-free in USA & Canada 800-677-9299 9 am - 5 pm (EST) M - F or visit [www.esbalabs.com](http://www.esbalabs.com)

**Label on tube and outer carton**

**Lipocaine 5 tube 113 grams label**

Lidocaine formulated in liposomes for *fast skin numbing* - in a cream with 100% naturally derived ingredients, with a natural preservative system.

**ALCOHOL FREE - no stinging!**

**NO: parabens, PEGs, propyleneglycol, artificial color or fragrance, mineral oil.**



**Drug Facts**

Active ingredient	Purpose
Lidocaine 5%.....	Topical Anesthetic

**Use** For temporary relief of pain and itching due to anorectal disorders.

**Warnings** For external use only.

**When using this product** ● avoid contact with eyes ● do not use in large quantities, particularly over raw surfaces or blistered areas ● do not put in rectum ● do not exceed recommended dosage unless directed by a doctor.

**Stop use and ask a doctor if** ● allergic reaction occurs ● rectal bleeding occurs ● condition worsens or does not improve within 7 days ● symptoms clear up and return within a few days ● redness, irritation, swelling, pain or other symptoms begin or increase.

**Keep out of the reach of children** If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Directions** ● When practical, clean area with mild soap and warm water and rinse thoroughly ● Gently dry by patting or blotting with toilet tissue or soft cloth before applying ● Adults and children 12 years old and older: Apply externally to the affected area up to 6 times a day ● Children under 12 years of age: consult a doctor.

**Other information**  
 ● Store at room temperature 20-25°C (68-77°F).  
 ● **Tamper Evident:** do not use if seal under cap is broken or missing.  
 ● **Child-Resistant Cap:** push down and turn to open.

**Inactive ingredients**  
 Allantoin, Aloe Barbadensis Leaf Extract, Beta-Sitosterol, Caprylhydroxamic Acid, Cetyl Alcohol, Cetyl Palmitate, Glycerin, Glyceryl Caprylate, Isostearyl Alcohol, Lecithin, Purified Water, Sucrose Distearate, Sucrose Stearate, Tocopheryl Acetate, Triethylcitrate, Xanthan Gum.

**Questions**  
 Call toll-free in USA & Canada **800-677-9299**  
 9 am - 5 pm (EST) M - F or visit **www.esbalabs.com**



Manuf. for:  
**ESBA Laboratories Inc.**  
 Jupiter FL 33458

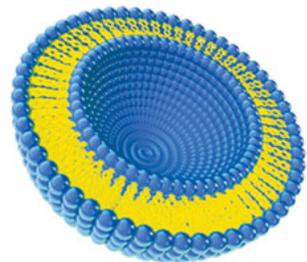
**MADE IN USA**

**LIPOCAINE 5**  
 ©  
**TOPICAL ANESTHETIC CREAM**  
**LIP**

NDC 63135-811-04

**Liposomal Lidocaine 5%**

**Topical Anesthetic Cream**



**Lidocaine in Liposomes for FAST AND DEEP SKIN NUMBING**



**ALCOHOL FREE**

**4 Oz (113 grams)**

**Lipocaine 5 tube 30 grams label**

**Drug Facts** (continued)

**Stop use and ask a doctor if:** ■ allergic reaction occurs ■ rectal bleeding occurs  
■ condition worsens or does not improve within 7 days ■ symptoms clear up and return within a few days ■ redness, irritation, swelling, pain or other symptoms begin or increase.

**Directions** ■ When practical, clean area with mild soap and warm water and rinse thoroughly ■ Gently dry by patting or blotting with toilet tissue or soft cloth before applying  
■ Adults and children 12 years and older: Apply externally to the affected area up to 6 times a day ■ Children under 12 years of age: consult a doctor.

Rev812

**SEE OUTER PACKAGE FOR COMPLETE DRUG FACTS**

[www.esbalabs.com](http://www.esbalabs.com)

Toll-Free USA/CAN 800-677-9299 M-F 9-5 pm (EST)

NDC 63135-811-30

Topical Anesthetic Cream

1 Oz (30 Grams)

**LIPOCAINE<sup>®</sup> 5**

Lidocaine 5% in Liposomes - ALCOHOL FREE - No Stinging!

**Drug Facts**

**Active ingredient**

Lidocaine 5% w/w .....Topical Anesthetic

**Purpose**

**Uses** For the temporary relief of pain and itching due to anorectal disorders.

**Warnings** For external use only.

**Flammable** Keep away from sparks, heat and fire. Cap tube tightly when not in use.

**When using this product** ■ avoid contact with eyes ■ do not use in large quantities, particularly over raw surfaces or blistered areas ■ do not put in rectum ■ do not exceed recommended dosage unless directed by a doctor.

Manuf. for:  **ESBA Laboratories Inc.** Jupiter FL 33458 **MADE IN USA**

**Outer carton of Lipocaine 5 - 30 g tube**



c100 m50

C41 Y 78 (similar to Pantone 375)



Beige (6% M+ 30% Y)



## LIPOCAINE 5

lidocaine 5% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63135-811
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	0.01 g in 100 g
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	1.5 g in 100 g
<b>SUCROSE DISTEARATE</b> (UNII: 33X4X4B90S)	2 g in 100 g
<b>.BETA.-SITOSTEROL</b> (UNII: S347WMO6M4)	0.5 g in 100 g
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	0.12 g in 100 g
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	0.6 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.48 g in 100 g
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	5 g in 100 g
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	0.25 g in 100 g

<b>WATER</b> (UNII: 059QF0KO0R)	71.77 g in 100 g
<b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)	0.25 g in 100 g
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	0.01 g in 100 g
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	10 g in 100 g
<b>SUCROSE STEARATE</b> (UNII: 274KW0050M)	2 g in 100 g
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	0.5 g in 100 g
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.01 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63135-811-30	1 in 1 CARTON	03/18/2019	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63135-811-04	113 g in 1 TUBE; Type 0: Not a Combination Product	03/18/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/18/2019	

**Labeler** - ESBA LABORATORIES INC. (963303490)

**Registrant** - Esba Laboratories Inc (963303490)

Revised: 1/2026

ESBA LABORATORIES INC.