

**TOPICAINE- lidocaine 4% gel**  
**ESBA LABORATORIES INC.**

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**TOPICAINE**

***Active ingredient***

Lidocaine 4% w/w

***Purpose***

Topical Anesthetic

***Uses***

For the temporary relief of pain.

***Warnings***

***For external use only***

***Flammable***

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

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

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- you notice any unusual effects

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

If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

Apply externally to affected area up to 3 to 4 times a day. Children under 2 years of age consult a doctor.

***Inactive Ingredients***

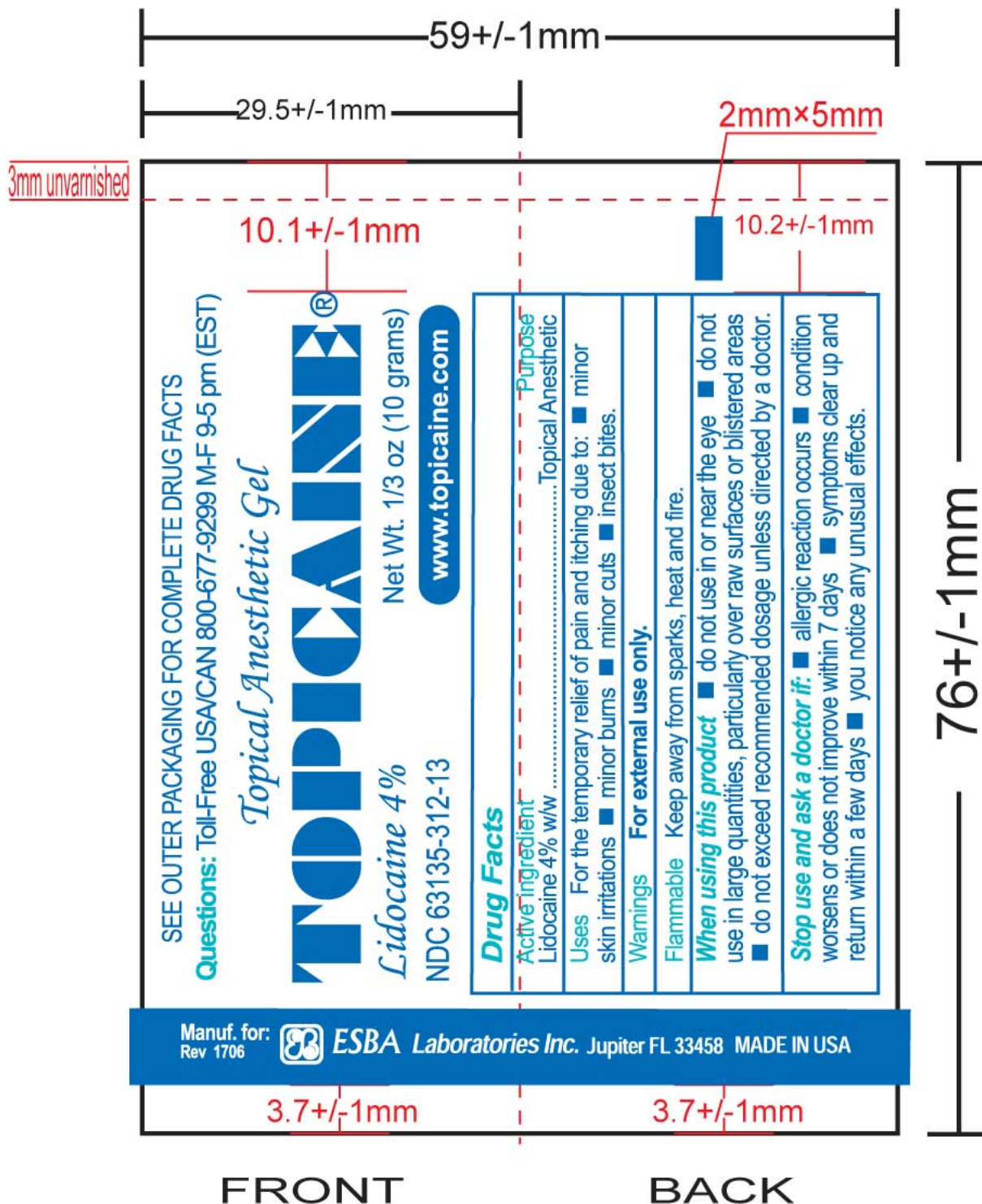
Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Laurate, SD Alcohol 40B, Simmondsia Chinensis (Jojoba) Seed Oil, Water

## Questions

Call toll-free in USA & Canada 800-677-9299 or visit [www.topicaïne.com](http://www.topicaïne.com)

## Labelling on tubes and outer cartons

Labelling printed on tube of Topicaïne 4% 10 gram tube:



**Outer carton of Topicaïne 4% 10 grams:**



**Label affixed to Topicaïne 4% 30 gram tubes:**

Manuf. for: Rev 1001  
**ESBA Laboratories Inc.** Jupiter FL 33458 MADE IN USA

<b>Drug Facts (continued)</b>	
<b>When using this product</b> ■ do not use in or near the eye ■ do not use in large quantities, particularly over raw surfaces or blistered areas ■ do not exceed recommended dosage unless directed by a doctor	
<b>Stop use and ask a doctor if:</b> ■ allergic reaction occurs ■ condition worsens or does not improve within 7 days ■ symptoms clear up and return within a few days ■ you notice any unusual effects	
<b>Keep out of the reach of children</b> If swallowed, get medical help or Contact a Poison Control Center right away	
<b>Directions</b> ■ Adults and children 2 years and older: Apply externally to the affected area up to 3 to 4 times a day ■ Children under 2 years of age: consult a doctor	
SEE OUTER PACKAGE FOR COMPLETE DRUG FACTS	

NDC 63135-312-30

Topical Anesthetic Gel

**TOPICAINE®**

Lidocaine 4%  
 www.topicaïne.com

Net Wt 1 oz (30 grams)  
 800-677-9299

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Lidocaine 4% w/w	Topical Anesthetic
<b>Uses</b> For the temporary relief of pain and itching due to : ■ minor skin irritations ■ minor burns ■ minor cuts ■ insect bites	
<b>Warnings</b> For external use only	
<b>Flammable</b> Keep away from sparks, heat and fire. Cap tube tightly when not in use. ▼	

**Outer box of Topicaïne 4% 30 grams:**

NDC 63135-312-30

Topical Anesthetic Gel

**TOPICAINE®**

Lidocaine 4%

Net Wt. 1 Oz (30 grams)

Topical Anesthetic Gel

**TOPICAINE®**

Lidocaine 4% www.topicaïne.com

Manuf. for: **ESBA LABORATORIES Inc.** Rev 511  
 Jupiter FL 33458 MADE IN USA

Topical Anesthetic Gel

**TOPICAINE®**

Lidocaine 4% www.topicaïne.com  
 Net Wt. 1 Oz (30 grams) 800-677-9299

UPC Symbol:  
 363135312302  
 (UCC-12)

www.topicaïne.com  
 800-677-9299

**TOPICAINE®**  
 is a registered trademark of  
 ESBA LABORATORIES Inc.

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Lidocaine 4% w/w	Topical Anesthetic
<b>Uses</b> For the temporary relief of pain and itching due to : ■ minor skin irritations ■ minor burns ■ minor cuts ■ insect bites	
<b>Warnings</b> For external use only	

<b>Drug Facts (continued)</b>	
<b>Flammable</b> Keep away from sparks, heat and fire. Cap tube tightly when not in use.	
<b>When using this product</b> ■ do not use in or near the eye ■ do not use in large quantities, particularly over raw surfaces or blistered areas ■ do not exceed recommended dosage unless directed by a doctor	
<b>Stop use and ask a doctor if:</b> ■ allergic reaction occurs ■ condition worsens or does not improve within 7 days ■ symptoms clear up and return within a few days ■ you notice any unusual effects such as blurred vision, dizziness or drowsiness, difficulty breathing, trembling, chest pain, or irregular heartbeat. ▼	

<b>Drug Facts (continued)</b>	
<b>Keep out of the reach of children</b> If swallowed, get medical help or Contact a Poison Control Center right away	
<b>Directions</b> ■ Adults and children 2 years and older: Apply externally to the affected area up to 3 to 4 times a day ■ Children under 2 years of age: consult a doctor	
<b>Inactive Ingredients</b> Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Laurate, SD Alcohol 40, Simmondsia Chinensis (Jojoba) Seed Oil, Water.	

**Label affixed to tubes of Topicaïne 4% 113 grams:**



NDC 63135-312-04

# Topical Anesthetic Gel

Lidocaine Gel 4 %

## Drug Facts

Active ingredient	Purpose
Lidocaine 4 % w/w.....	Topical Anesthetic

**Uses** For the temporary relief of pain and itching due to minor: ■ skin irritations ■ burns ■ cuts ■ insect bites.

**Warnings** *For external use only*

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

**When using this product**

- do not use in or near the eye
- do not use in large quantities, particularly over raw surfaces or blistered areas
- do not exceed recommended dosage unless directed by a doctor.

**Stop use and ask a doctor if**

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- you notice any unusual effects.

**Keep out of the reach of children**  
If swallowed, get medical help or contact a Poison Control Center right away.



**Directions** ■ Adults and children 2 years and older: apply externally to the affected area up to 3 to 4 times a day ■ Children under 2 years of age: consult a doctor.

**Inactive Ingredients** Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Laurate, Glycine Soja (Soybean) Oil, SD Alcohol 40B, Simmondsia Chinensis (Jojoba) Seed Oil, Water.

**Questions** Call toll-free in USA & Canada 800-677-9299 or visit [www.topicaine.com](http://www.topicaine.com)



Manuf. for:

**ESBA Labs Inc.**

Jupiter FL 33458

MADE IN USA

**NET WEIGHT 4 Oz (113 Grams)**

## TOPICAINE

lidocaine 4% gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63135-312
<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	4 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	44.534 g in 100 g
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	0.6 g in 100 g

<b>ALCOHOL</b> (UNII: 3K9958V90M)	36.842 g in 100 g
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	2.5 g in 100 g
<b>GLYCERYL LAURATE</b> (UNII: Y98611C087)	2 g in 100 g
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	2.5 g in 100 g
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	2 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	5 g in 100 g
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	0.024 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63135-312-30	1 in 1 BOX	04/20/2003	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63135-312-13	1 in 1 BOX	04/20/2003	
2		10 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:63135-312-04	113 g in 1 TUBE; Type 0: Not a Combination Product	04/20/2003	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/20/2003	

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

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

Revised: 9/2024

ESBA LABORATORIES INC.