

TOPICAINE- lidocaine 4% gel
ESBA LABORATORIES 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.

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

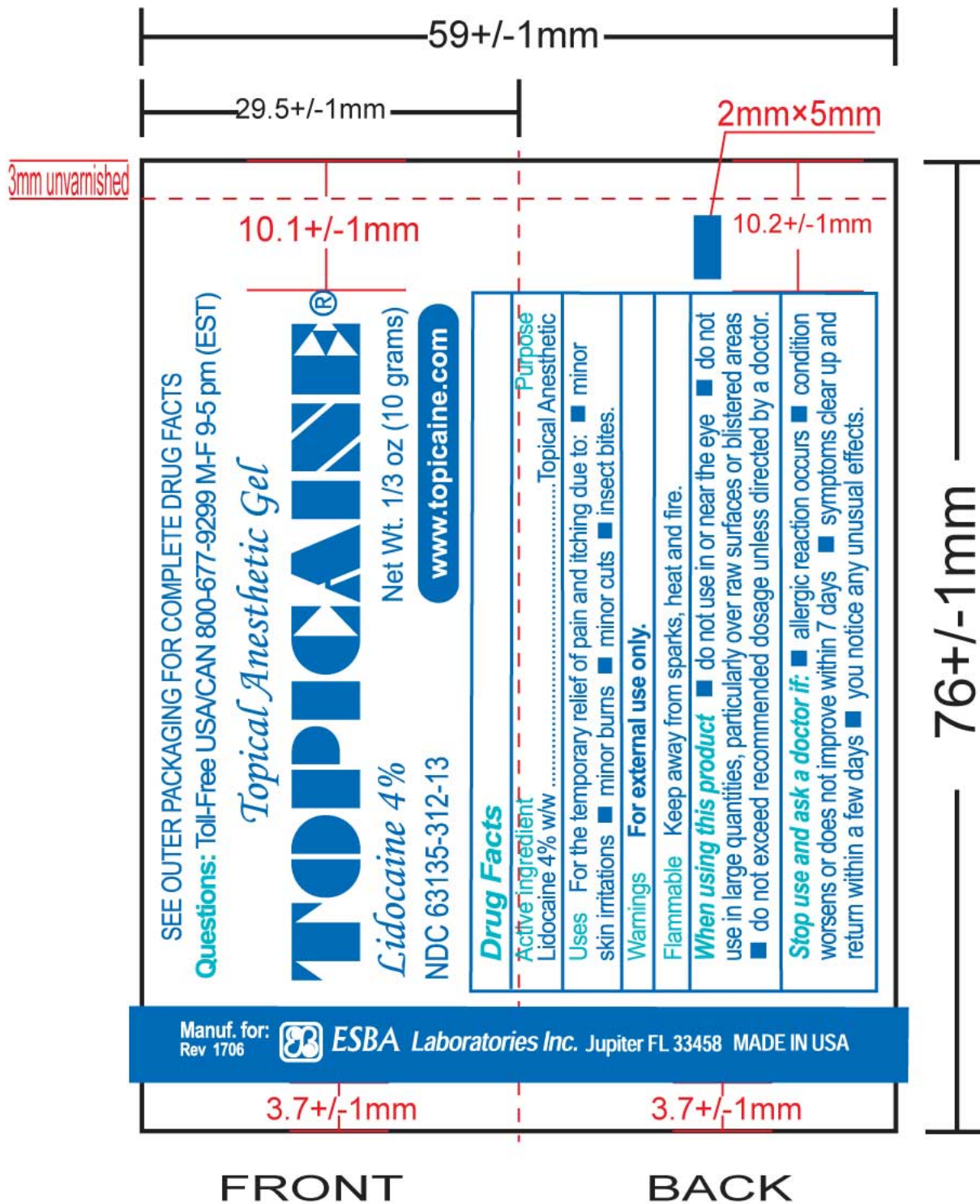
Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Disodium EDTA, Glycerin, Glyceryl Laurate, SD Alcohol 40B, Simmondsia Chinensis (Jojoba) Seed Oil, Water

Questions

Call toll-free in USA & Canada 800-677-9299 or visit www.topicaïne.com

Labelling on tubes and outer cartons

Labelling printed on tube of Topicaine 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

Drug Facts (continued)

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

SEE OUTER PACKAGE FOR COMPLETE DRUG FACTS

NDC 63135-312-30

Topical Anesthetic Gel
TOPICAÏNE[®]
 Lidocaine 4%
 www.topicaïne.com

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

Drug Facts

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

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


Warnings **For external use only**

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

Outer box of Topicaïne 4% 30 grams:



Label affixed to tubes of Topicaïne 4% 113 grams:



NDC 63135-312-04

Topical Anesthetic Gel

Lidocaine Gel 4 %

<h3>Drug Facts</h3>	
Active ingredient Lidocaine 4 % w/w.....	Purpose 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.	



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.topicalaine.com



Manuf. for:



ESBA Labs Inc.
Jupiter FL 33458

MADE IN USA

NET WEIGHT 4 Oz (113 Grams)

TOPICAINE

lidocaine 4% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63135-312
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	44.534 g in 100 g
CARBOMER 940 (UNII: 4Q93RCW27E)	0.6 g in 100 g
ALCOHOL (UNII: 3K9958V90M)	36.842 g in 100 g
JOJOBA OIL (UNII: 724GKU717M)	2.5 g in 100 g
GLYCERYL LAURATE (UNII: Y98611C087)	2 g in 100 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	2.5 g in 100 g
BENZYL ALCOHOL (UNII: LKG8494WBH)	2 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	5 g in 100 g
EDETATE DISODIUM (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 final	part346	04/20/2003	

Labeler - ESBA LABORATORIES INC. (963303490)

Registrant - ESBA LABORATORIES INC. (963303490)

Establishment

Name	Address	ID/FEI	Business Operations
ESBA LABORATORIES INC		963303490	manufacture(63135-312)

Revised: 12/2021

ESBA LABORATORIES INC.