

TOPICAINE 5- lidocaine 5% 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 5

Active Ingredient

Lidocaine 5% w/w

Purpose

Topical Anesthetic

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

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.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Bisabolol, Benzyl Alcohol, Carbomer, Disodium EDTA,

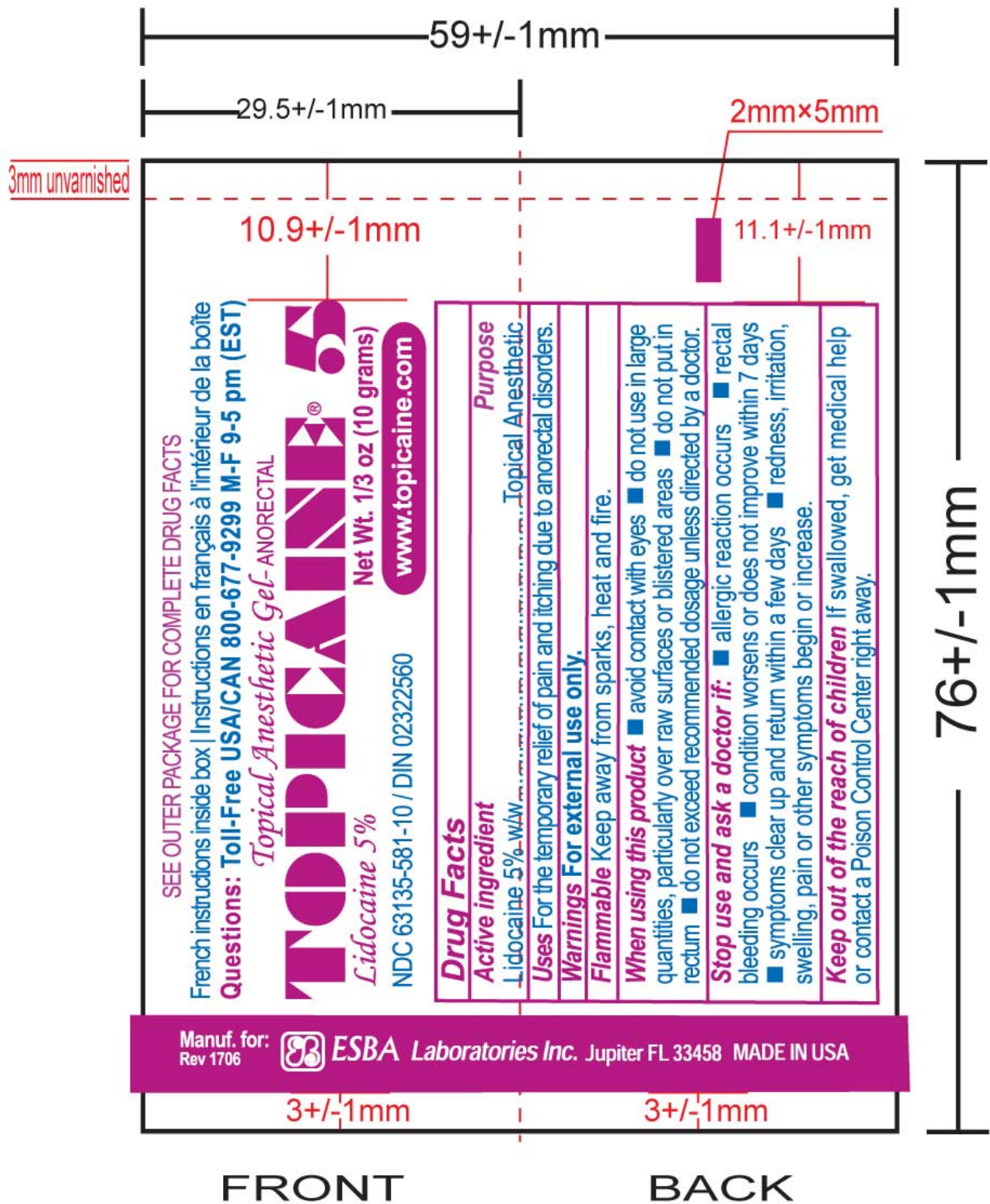
Glycerin, Glyceryl Laurate, SD Alcohol 40, Shea Butter, Simmondsia Chinensis (Jojoba) Seed Oil, Water.

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.

Label on tube and outer carton

Labeling printed on tube of Topicaïne 5% 10 g



Outer carton of Topicaïne 5% 10 g tube



Label affixed to tube of Topical Anesthetic Gel (Lidocaine 5%) 30 g tube

Manuf. for:
Rev 1/07



ESBA Laboratories Inc. Jupiter FL 33458 MADE IN USA
French instructions inside box | Instructions en français à l'intérieur de la boîte

Drug Facts (continued)

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SEE OUTER PACKAGE FOR COMPLETE DRUG FACTS

www.topicaïne.com

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

NDC 63135-581-10 / DIN 02322560

Topical Anesthetic Gel- ANORECTAL

TOPICAÏNE® 5

Lidocaine 5%

Net Wt 1 Oz (30 grams)

Drug Facts

Active ingredient

Lidocaine 5% w/w **Purpose** Topical Anesthetic

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

Warnings For external use only.

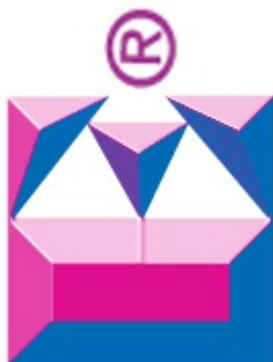
Flammable Keep away from sparks, heat and fire. Cap tube tightly when not in use.

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.

Outer carton of Topicaïne 5 % 30 g tube:



Label affixed to tube to Topicaïne 5% 113 g



DIN 02322560 NDC 63135-581-04
Topical Anesthetic Gel - Anorectal
Lidocaine Gel 5%

Drug Facts

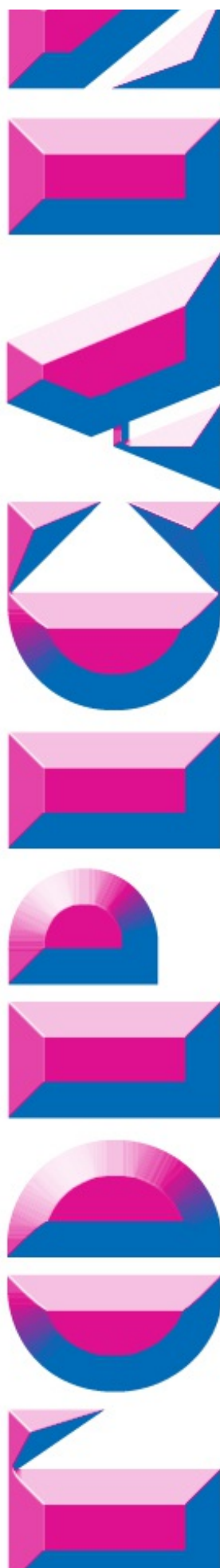
Active ingredient **Purpose**
Lidocaine 5 % w/w.....Topical Anesthetic

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

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Inactive Ingredients Aloe Barbadensis Leaf Extract, Bisabolol, Benzyl Alcohol, Butyrospermum Parkii (Shea Butter) 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.topicaline.com



Manuf. for:

ESBA Labs Inc.

MADE IN USA



Jupiter FL 33458

NET WEIGHT 4 Oz (113 Grams)

TOPICAINE 5

lidocaine 5% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63135-581
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	5 g in 100 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	2 g in 100 g
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.8 g in 100 g
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	1 g in 100 g
SHEA BUTTER (UNII: K49155WL9Y)	2.5 g in 100 g
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.025 g in 100 g
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.6 g in 100 g
GLYCERYL LAURATE (UNII: Y98611C087)	2.5 g in 100 g
ALCOHOL (UNII: 3K9958V90M)	36.75 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63135-581-30	1 in 1 BOX	04/20/2003	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63135-581-10	1 in 1 BOX	04/20/2003	
2		10 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:63135-581-04	113 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/20/2003	12/31/2025

Labeler - ESBA LABORATORIES INC. (963303490)

Registrant - ESBA LABORATORIES INC. (963303490)

Establishment

Name	Address	ID/FEI	Business Operations
ESBA LABORATORIES INC.		963303490	manufacture(63135-581)

Revised: 7/2023 ESBA LABORATORIES INC.