

TOPICAINE 5- lidocaine 5% gel
ESBA LABORATORIES INC.

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.

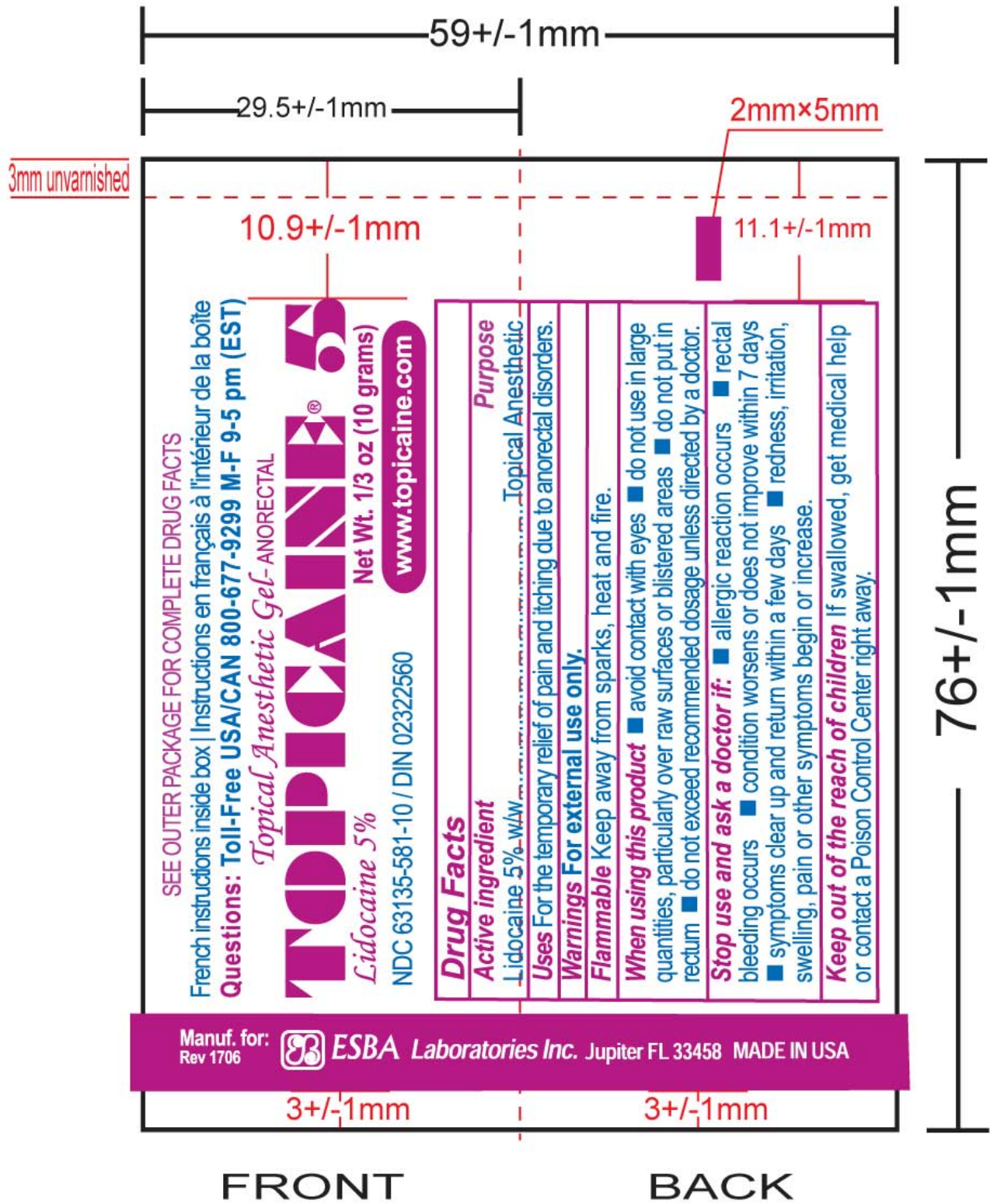
Inactive Ingredients

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 Topicaïne 5 % 30 g tube

Manuf. for:
Rev 17/07



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)

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.

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
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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

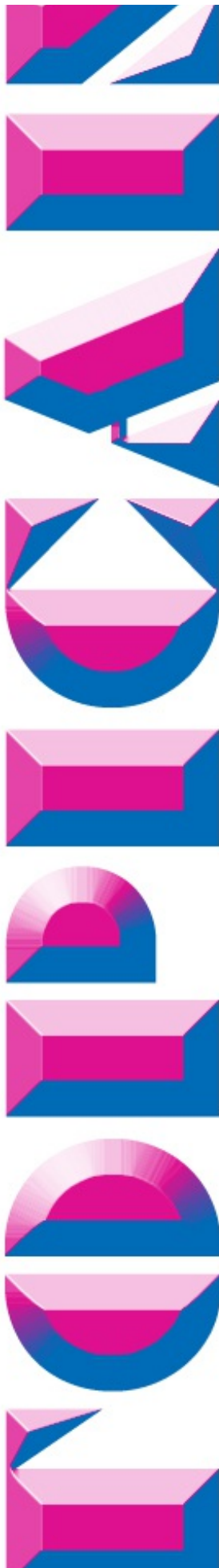
| | |
|--------------------------|--------------------|
| Active ingredient | Purpose |
| Lidocaine 5 % w/w..... | Topical Anesthetic |

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

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.

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.

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.topicaïne.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 Drug | M015 | 04/20/2003 | |

Labeler - ESBA LABORATORIES INC. (963303490)

Registrant - ESBA LABORATORIES INC. (963303490)

Revised: 9/2024

ESBA LABORATORIES INC.