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.

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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 Topicaine 5% 10 g
Label affixed to tube of Topicaine 5% 30 g tube
Outer carton of Topicaine 5 % 30 g tube:
Label affixed to tube to Topicaine 5% 113 g
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, Butyroserum Parkii (Shea Butter) Carbomer, Disodium EDTA, Glycerin, Glycerin Laurate, Glycine Soja (Soybean) Oil, SD Alcohol 40B, Simmondsia Chi- nensis (Jojoba) Seed Oil, Water.

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

Manuf. for: ESBA Labs Inc. 1-877-372-4527 MADE IN USA
TOPICAINE 5
lidocaine 5% gel

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

Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)</td>
<td>LIDOCAINE</td>
<td>5 g in 100 g</td>
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Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>GLYCERIN (UNII: PDC6A3C00X)</td>
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<tr>
<td>ALOE VERA LEAF (UNII: ZY81Z83H0X)</td>
<td>2 g in 100 g</td>
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<tr>
<td>BENZYL ALCOHOL (UNII: LKG8494WBH)</td>
<td>0.8 g in 100 g</td>
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<td>ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)</td>
<td>1 g in 100 g</td>
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<td>SHEA BUTTER (UNII: K49155WL9Y)</td>
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<tr>
<td>EDETATE DISODIUM (UNII: 7FLD91C86K)</td>
<td>0.025 g in 100 g</td>
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<td>POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)</td>
<td>0.6 g in 100 g</td>
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<tr>
<td>GLYCERYL LAURATE (UNII: Y98611C087)</td>
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<td>ALCOHOL (UNII: 3K9958V90M)</td>
<td>36.75 g in 100 g</td>
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Packaging

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<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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Marketing Information

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<tr>
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<tr>
<td>OTC monograph final</td>
<td>part346</td>
<td>04/20/2003</td>
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Revised: 1/2019