

## **RECTAL CARE CREAM REVIVOL- lidocaine 5% cream**

### **Derma Care Research Labs**

*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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### **Rectal Care**

Lidocaine 5.0%

Local Anesthetic

### **Uses**

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

### **For external use only.**

**When using this product** avoid contact with eyes, do not exceed recommended dosage unless directed by a doctor, do not put this product into the rectum by using fingers or any mechanical device or applicator.

**Stop use and ask a doctor if** rectal bleeding occurs, condition worsens or does not improve within 7 days, allergic reaction occurs to ingredients in this product, symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, or symptoms clear up and return within a few days.

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

- When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: consult a doctor.
- To use finger cots: roll one finger cot over a finger. Gently squeeze cream onto finger cot. Smooth a layer of the cream over the affected area

Aloe Barbadensis Leaf Extract, Benzyl Alcohol, Carbomer, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water

**RēVIVOL-XR®**  
HELPS GET YOU BACK TO YOUR NORMAL LIFE™

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5% LIDOCAINE | SOOTHING ALOE | VITAMIN E

NDC 72839-141-01

MAXIMUM STRENGTH

**Hemorrhoid Cream**  
Rapid Pain Relief for Hemorrhoids & Other Anorectal Disorders

Relieves Pain • Relieves Itching • Relieves Burning



5% LIDOCAINE | SOOTHING ALOE | VITAMIN E

NDC 72839-141-01

MAXIMUM STRENGTH

**Hemorrhoid Cream**  
Rapid Pain Relief for Hemorrhoids & Other Anorectal Disorders

Relieves Pain • Relieves Itching • Relieves Burning

Net Wt 1.0 OZ (28 g)



Scan with your  
Transparency app.  
To learn about:  
• Authenticity  
• Origins  
• Product Date  
• And more



ReVIVOL-XR Plus | 5% Lido... Non-Greasy | Made in USA



Distributed by:  
Tenet Solutions, LLC  
7750 Okeechobee Blvd  
Suite #4-674  
West Palm Beach, FL 33411  
info@hemorrhoid.com  
www.hemorrhoid.com

**SCAN NOW**

Learn How To  
Use & Get Your  
Best Results.

**Drug Facts (continued)**  
**Inactive ingredients** water, isopropyl myristate, poly sorbate 80, propylene glycol, benzyl alcohol, aloe barbadensis leaf extract, tocopheryl acetate, cholesterol, hydrogenated lecithin, carbomer, triethanolamine

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Lidocaine 5.0%.....Local anesthetic</p> <p><b>Uses</b> Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders</p> <p><b>Warnings</b> For external use only.</p> <p><b>When using this product</b> • avoid contact with eyes • do not exceed recommended dosage unless directed by a doctor • do not put this product into the rectum by using fingers or any mechanical device or applicator</p> <p><b>Stop use and ask a doctor if</b> • rectal bleeding occurs • condition worsens or does not improve within 7 days • allergic reaction occurs to ingredients in this product • symptom being treated does not subside or if return within a few days</p> <p><b>Questions?</b> (561) 247-5134 • Hemorrhoid.com "How To Use" Help? - Scan QR Code by Phone Camera. See the panel below</p>	<p><b>Drug Facts (continued)</b> If pregnant or breastfeeding, ask a health professional before use</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away</p> <p><b>Directions</b> • 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 and older: apply externally to the affected area up to 6 times a day • Children under 12 years of age: consult a doctor</p> <p><b>Other information</b> Store at 15°-30° C (59°-86° F)</p>
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**RECTAL CARE CREAM REVIVOL**

lidocaine 5% cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-141
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>			<b>Basis of Strength</b>	<b>Strength</b>
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)			LIDOCAINE	5 g in 100 g
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-141-01	28 g in 1 TUBE; Type 0: Not a Combination Product	03/26/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	03/26/2020		

**Labeler** - Derma Care Research Labs (116817470)

**Registrant** - Derma Care Research Labs (116817470)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-141)