

**DR. NUMB - lidocaine cream**  
**Ei 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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**Dr. Numb Anorectal Cream**

**Active Ingredients Purpose**

Lidocaine 5% Local Anesthetic

**Uses**

For temporary relief of local discomfort, itching pain, soreness or burning in the perianal area associated with anorectal disorders. For temporary relief of local discomfort, itching pain, soreness or burning in the perianal area associated with anorectal disorders.

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

For temporary relief of local discomfort, itching, pain, soreness or burning in the perianal area associated with anorectal disorders.

**Warnings**

**For external use only**

**When using this product**

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

- allergic reaction occurs
- redness, irritation, swelling, pain, or other symptoms begin or increase
- condition worsens or does not improve within 7 days

**Directions**

- adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before application of this product
- when first opening the tube, twist the cap and peel off the foil seal
- apply externally to the affected area up to 6 times daily
- children under 12 years of age: consult a doctor

**Inactive ingredients**

Carbopol, lecithin, propylene glycol, purified water, vitamin E.

**Other information**

- always keep the tube tightly closed
- store at temperatures not exceeding 15°C- 30°C
- protect from freezing

**Questions and comments?**

Call weekdays 8 a.m. to 5 p.m. PST at **8-877-786-2001** or email us at [support@drnumb.com](mailto:support@drnumb.com)

**Labeling**

<p>Net Wt. 1.06oz (30g)</p>		<h1>Dr. Numb</h1> <p>Anorectal Cream</p>		<p>NDC 52512-130-30</p>
<p><b>Maximum Strength Pain Reliever</b>  <i>Helps relieve the itching and discomfort associated with hemorrhoids &amp; anorectal disorders.</i></p>				
<p><b>Drug Facts</b></p> <p><b>Active ingredient</b></p> <p>Lidocaine 5% ..... <b>Purpose</b> Local Anesthetic</p>		<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>when first opening the tube, twist the cap and peel off the foil seal</li> <li>apply externally to the affected area up to 6 times daily</li> <li>children under 12 years of age: consult a doctor</li> </ul>		
<p><b>Uses</b></p> <p>For temporary relief of local discomfort, itching, pain, soreness or burning in the perianal area associated with anorectal disorders.</p>		<p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>always keep the tube tightly closed</li> <li>store at temperatures not exceeding 15°C - 30 °C</li> <li>protect from freezing.</li> </ul>		
<p><b>Warnings</b></p> <p><b>For external use only</b></p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>do not exceed the recommended daily dosage unless directed by a doctor</li> <li>do not put into the rectum by using fingers or any mechanical device or applicator</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>allergic reaction occurs</li> <li>rectal bleeding occurs</li> <li>redness, irritation, swelling, pain, or other symptoms begin or increase</li> <li>condition worsens or does not improve within 7 days</li> </ul> <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>Inactive ingredients</b> carbopol, lecithin, propylene glycol, purified water, vitamin E</p> <p><b>Questions or comments?</b> Call weekdays 8 AM to 5 PM PST at 1-877-786-2001 or email us at <a href="mailto:support@drnumb.com">support@drnumb.com</a></p>		
<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product</li> </ul>		<p>Manufactured by EI Inc.                  Kannapolis, NC 28083 U.S.A.                  Dr. Numb® is a registered trademark of ShinSachi Pharmaceutical Inc.</p>		
		 <p>6 27843 07480 9</p>		

Prompt, Soothing Relief from  
Painful Burning, Itching and Discomfort

5% LIDOCAINE

FOR EXTERNAL USE ONLY

**Dr. Numb** Anorectal Cream

Net Wt.  
1.06oz (30g)

NDC 52512-130-30

**Dr. Numb**<sup>®</sup>  
Anorectal Cream

**Maximum Strength Pain Reliever**

Helps relieve the itching and discomfort associated with hemorrhoids & anorectal disorders.

Dr. Numb<sup>®</sup>  
Anorectal Cream

Dr. Numb<sup>®</sup>  
Anorectal Cream



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Kannapolis, NC 28083 U.S.A.  
Manufactured by E Inc.

**Drug Facts (continued)**

**Active ingredient** Lidocaine 5% Local Anesthetic

**Uses**  
For temporary relief of local discomfort, itching, pain, soreness or burning in the perianal area associated with anorectal disorders.

**Warnings**  
For external use only

**When using this product**  
do not exceed the recommended daily dosage unless directed by a doctor  
do not put into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**  
single reaction occurs  
rectal bleeding occurs  
redness, irritation, swelling, pain, or other symptoms begin or increase  
condition worsens or does not improve within 7 days

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

**Directions**  
adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

**Drug Facts**

**Other information**  
always keep the tube tightly closed  
store at temperatures not exceeding 15°C - 30 °C  
protect from freezing

**Inactive ingredients** carboxyl, kedthyn, propylene glycol, purified water, vitamin E

**Questions or comments?** Call weekdays 8 AM to 5 PM PST at 1-877-786-2001 or email us at support@drnumb.com

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Kannapolis, NC 28083 U.S.A.  
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**DR. NUMB**

lidocaine cream

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52512-130
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>Lidocaine</b> (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)		Lidocaine	5 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
Propylene Glycol (UNII: 6DC9Q167V3)				
Benzyl Alcohol (UNII: LKG8494WBH)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:52512-130-30	1 in 1 PACKAGE		
1		30 g in 1 TUBE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part348	11/15/2012		

**Labeler** - Ei Inc. (105803274)

**Registrant** - Ei Inc. (105803274)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(52512-130) , label(52512-130) , pack(52512-130)