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.

Dr. Numb Anorectal Cream

Acive Ingredients Purpose

Lidocaine 5% Local Anesthetic

Uses

For temprary relief of local discomfort, itching pain, soreness or burning in the perianal area associated with anorectal disorders. For temprary 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 assosiated 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 simptoms begin or increase
- condition worsens or does not improve withing 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.

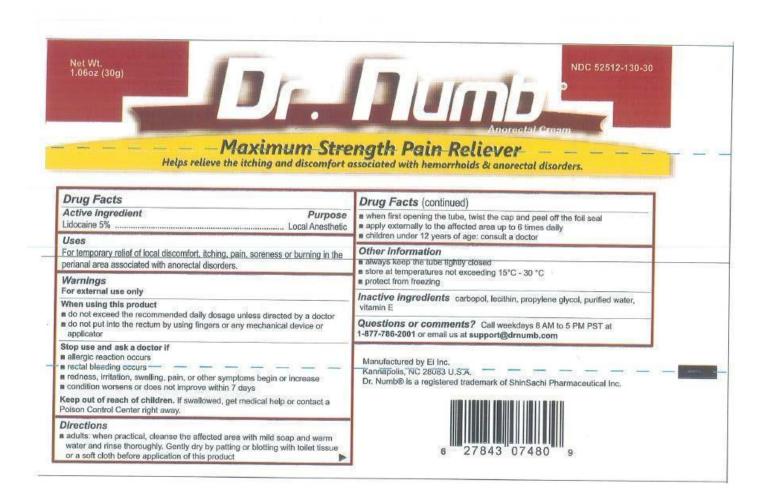
Other information

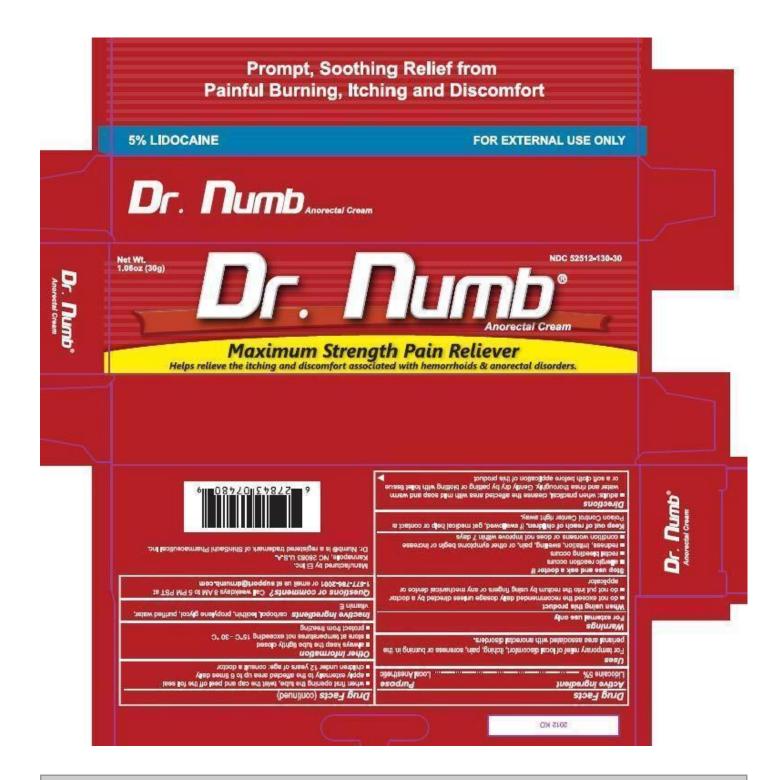
- always keep the tube tightly closed
- store at temperatures not exceeding 15⁰⁰C- 30⁰⁰C
- protect from freezing

Questions and comments?

Call weekdays 8 a.m. to 5 p.m. PST at **8-877-786-2001** oe email us at **support@drnumb.com**

Labeling





DR. NUMB

lidocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52512-130
Route of Administration	TOPICAL		
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Active Ingredient/Active Moiety			
Ingre	dient Name	Basis of Stren	igth Strength
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Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lido ca ine	5 g	in 100	g
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Inactive Ingredients		
Ingredient Name	Strength	
Propylene Glycol (UNII: 6DC9Q167V3)		
Benzyl Alcohol (UNII: LKG8494WBH)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)		
CARBOMER HOMOPOLYMER TYPE B (UNII: HHT01ZNK31)		

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:52512-130-30	1 in 1 PACKAGE			
1		30 g in 1 TUBE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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)

Revised: 12/2012 Ei Inc.