

**RECTOPROTECT- lidocaine cream**  
**Akron Pharma Inc.**

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**RectoProtect (Lidocaine 5% Anorectal Cream)**

**Pain Relief for Hemorrhoids & Other Anorectal Disorders**

***Active ingredient***

Lidocaine 5% w/w

***Purpose***

Local anesthetic

***Uses***

temporarily relieves pain and itching due to anorectal disorders

***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 and older: Apply externally to the affected area up to 6 times a day.
- children under 12 years of age: Consult a doctor

***Warnings***

**When using this product**

- avoid contact with eyes
- do not exceed recommended dosage unless directed by a doctor

**Stop use and ask a doctor if**

- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- allergic reaction occurs
- redness, irritation, swelling, pain or other symptoms begin or increase
- symptoms clear up and return within a few days

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

## Other information

- May be applied under occlusive dressing.
- Store at room temperature, 20–25°C (68–77°F) Excursions permitted 15–30°C (59–86°F) [see USP Controlled Room Temperature].

## Inactive ingredients

Benzyl Alcohol, Carbopol 940, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine and Vitamin E Acetate.

## Questions or comments?

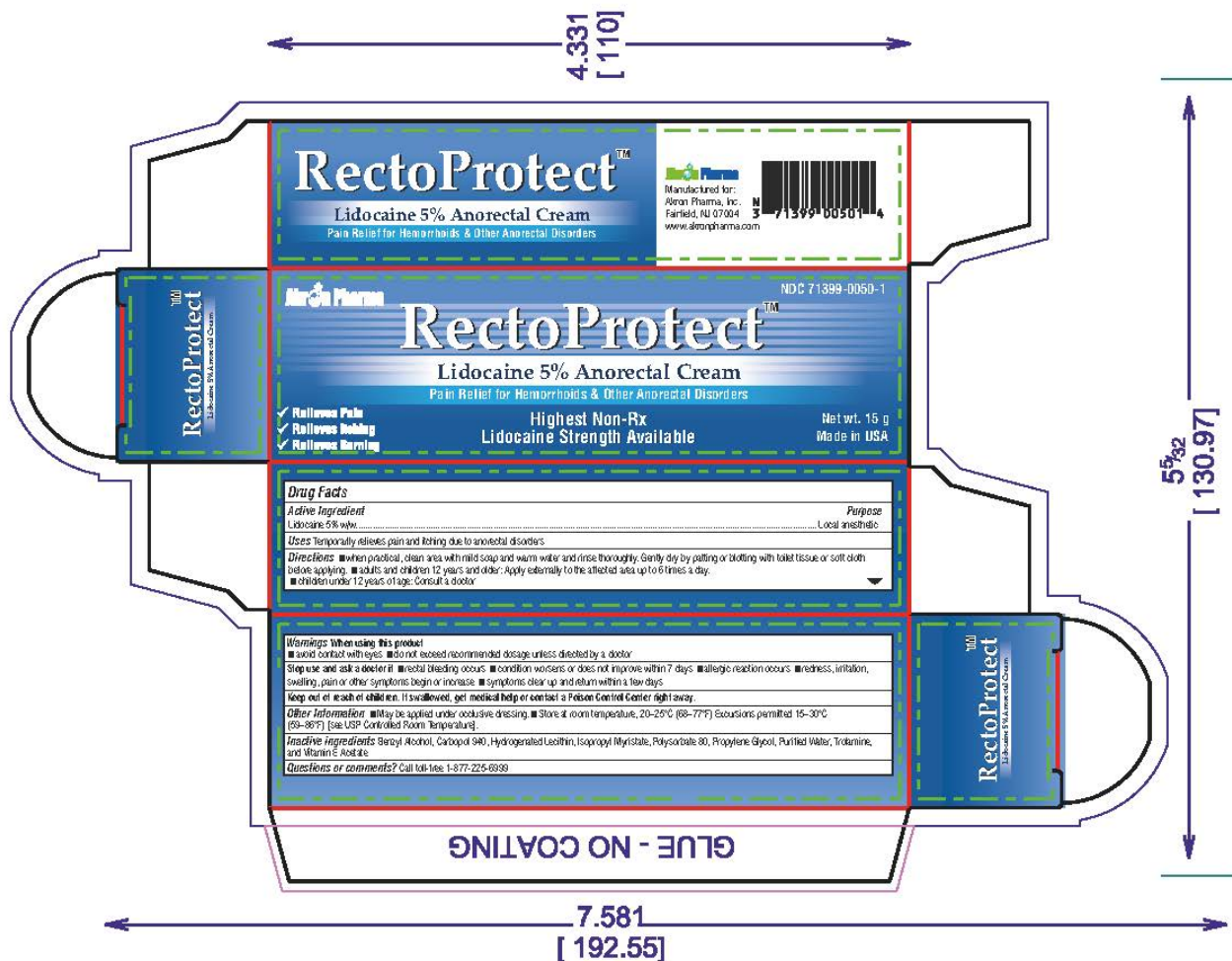
Call toll-free 1-877-255-6999

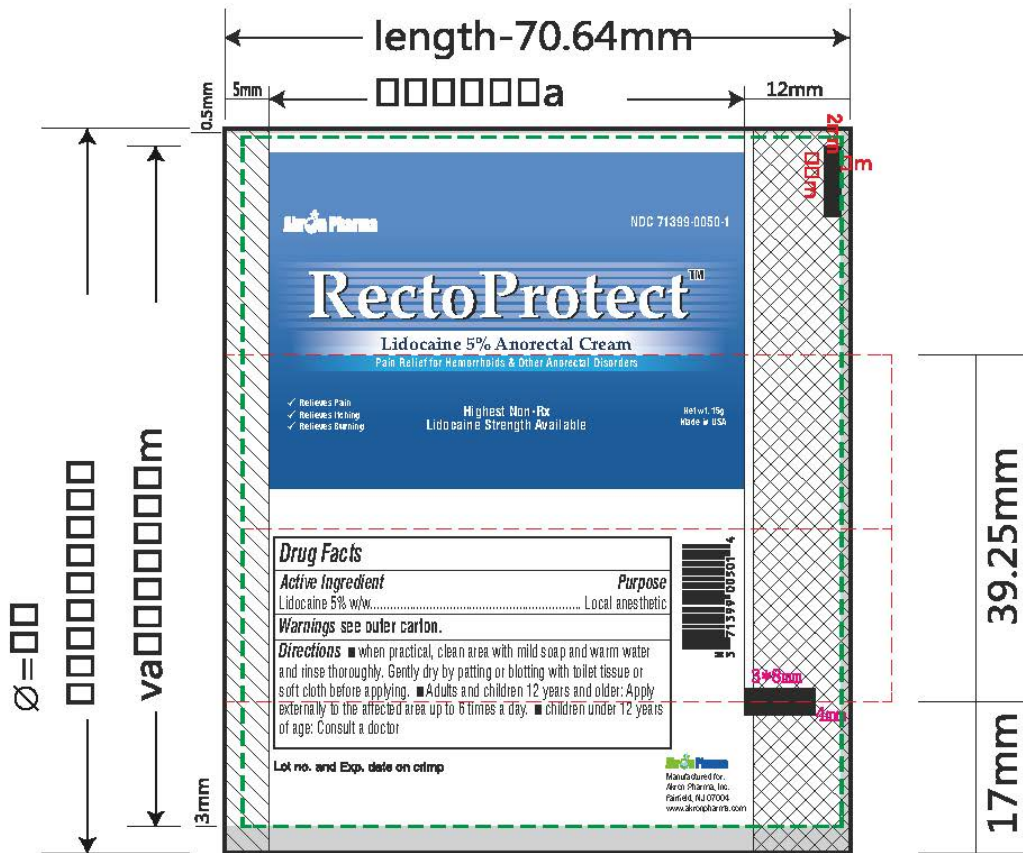
## Manufactured for:

Akron Pharma Inc.

Fairfield, Nj 07004

www.akronpharma.com









## RECTOPROTECT

lidocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71399-0050
<b>Route of Administration</b>	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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

### Product Characteristics

<b>Color</b>	white (clear gel)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0050-1	1 in 1 CARTON	11/03/2023	
1		5 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:71399-0050-2	1 in 1 CARTON	11/03/2023	
2		30 g in 1 PACKAGE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/03/2023	

**Labeler** - Akron Pharma Inc. (067878881)

Revised: 11/2023

Akron Pharma Inc.