

**HEMORRHOID RELIEF CREAM- lidocaine 5% anorectal cream**  
**ALAINA HEALTHCARE PRIVATE LIMITED**

*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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**Drug Facts**

**Active Ingredient**

Lidocaine 5% W/W

**Purpose**

Local Anesthetic

**Uses**

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

**Warnings**

**For external use only**

**When using this product**

- use only as directed.
- 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.
- symptoms clear up and occur again within a few days.
- an allergic reaction develops to ingredients in this product.
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

**If pregnant or breast-feeding**, ask a health professional before use.

**keep out of reach of children and pets.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

Adult and children 12 years and over:

- 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.
- apply externally to the affected area up to 6 times a day children under 12 years of age: consult a doctor.

**Other Information.**

- Store between 15°-30° C (59°-30° F).

**Inactive Ingredient**

Benzyl Alcohol, Carbomer 940, Cholesterol, Isopropyl Myristate, Lecithin (Soya), Polysorbate 80, Propylene Glycol, Purified Water, Triethanolamine, Vitamin-E Acetate.

**Questions or Comments? 1-888-287-1915****Manufactured By:**

Alaina Healthcare Private Limited  
Khasra No. 127-133, Baddi-Barotiwala Road,  
Baddi, HIMACHAL PRADESH 173205, India (IND).

**Distributed By:**

Walmart Inc., Bentonville, AR 72716. PRODUCT OF INDIA.

\*This product is not manufactured or distributed by Ferndale IP, Inc., Owner of the registered trademark RectiCare<sup>®</sup>.

**Package Label.Principal Display Panel**

**Hemorrhoid Relief Cream-Tube - NDC 73492-712-28 - Label.**

NDC 79903-109-30

**equate™**



- Helps relieve pain and burning
- For temporary relief of itching and discomfort associated with hemorrhoids and other anorectal disorders
- Highest lidocaine strength available over-the-counter

# Hemorrhoid Relief Cream

Lidocaine 5%  
Anorectal Cream

**NET WT 1 OZ (28g)**

**Drug Facts**

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION | TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING OR TUBE IS DAMAGED

Active ingredient	Purpose
Lidocaine 5% w/w.....	Local anesthetic

**Uses** helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders

**Warnings** See carton for complete warnings  
**For external use only**

**When using this product** ■ use only as directed ■ 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.

**If pregnant or breast-feeding**, ask a health professional before use.  
**Keep out of reach of children and pets.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

Adults and children 12 years and over:  
■ 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.  
■ apply externally to the affected area up to 6 times a day  
Children under 12 years of age: consult a doctor

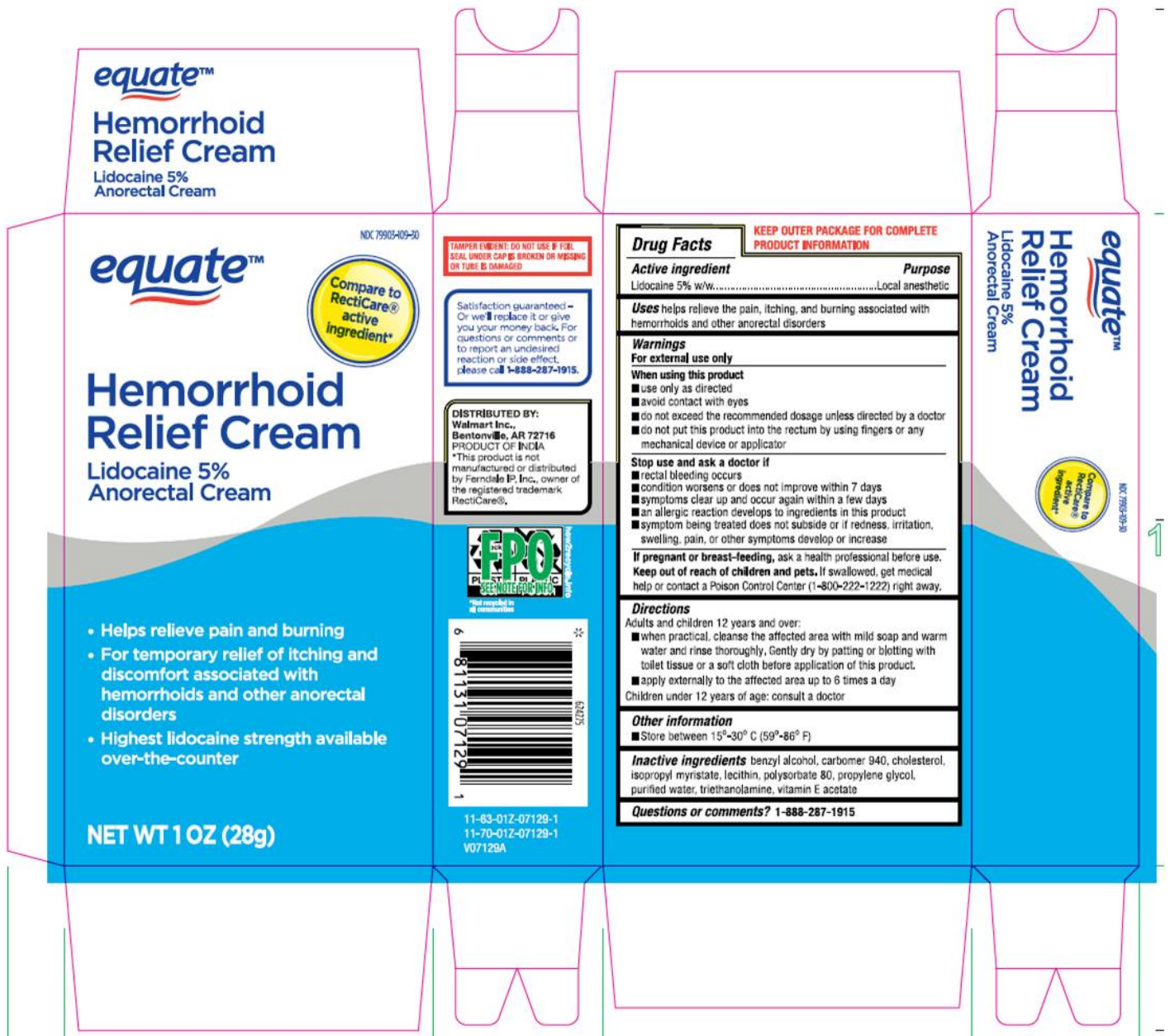
**Other information**  
■ Store between 15°-30° C (59°-86° F)

**Inactive ingredients**  
benzyl alcohol, carbomer 940, cholesterol, isopropyl myristate, lecithin, polysorbate 80, propylene glycol, purified water, triethanolamine, vitamin E acetate

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716 PRODUCT OF INDIA \*This product is not manufactured or distributed by Ferndale IP, Inc., owner of the registered trademark RectiCare®.

Not For Individual Retail Sale. V07129A

**Hemorrhoid Relief Cream-Tube - NDC 73492-712-28 - Carton.**



## HEMORRHOID RELIEF CREAM

lidocaine 5% anorectal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73492-712
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73492-712-28	1 in 1 CARTON	01/28/2022	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/28/2022	

**Labeler** - ALAINA HEALTHCARE PRIVATE LIMITED (858720927)

### Establishment

Name	Address	ID/FEI	Business Operations
ALAINA HEALTHCARE PRIVATE LIMITED		858720927	manufacture(73492-712)

Revised: 1/2022

ALAINA HEALTHCARE PRIVATE LIMITED