ANORECTAL HEMORRHOIDAL CREAM WITH LIDOCAINE 5%- lidocaine 5% cream cream ONE2ZEE LIMITED LIABILITY COMPANY

Annorectal (Hemorrhoidal) Cream with Lidocaine 5%

DRUG FACTS:

Active Ingredient:

Lidocaine HCI 5.0%

Purpose

Anorectal (Hemorrhoidal) Cream

Uses:

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

Warnings:

• **For external use only**. If condition worsens or does not improve within 7 days, consult a doctor.

When using this product,

- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.
- Keep out of reach of children.
- If swallowed, get medical help or contact the Poison Control Center immediately.
- If pregnant or breast feeding, ask a health professional before use.

Directions:

Children under 12: Consult a doctor.

Adults and children 12 years and older: For optimum results cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a clean, soft cloth before application of this product. Apply externally up to 6 times per day.

Keep out of reach of children.

Inactive Ingredients

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

Other Information:

Store at room temperature. Avoid direct sunlight. Do not use if tamper evident packaging has been breached or is missing. See bottom of this jar for lot number and expiry date.

Distributed by: Wellspring Airmont, NY 10952 U.S.A.

Packaging label for the tube

♦HEALTH ONE

ANORECTAL (HEMORRHOIDAL) CREAM

LIDOCAINE

WORKS FASTER **LASTS LONGER**

4oz | 113g

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active Ingredients Purpose

Lidocaine (5% w/w) Anorectal (Hemorrhoidal) Cream

Warnings

For external use only

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

Directions ■ Children under 12: Consult a doctor. ■ Adults and children 12 years and older: For optimum results cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a clean, soft cloth before application of this product. Apply externally up to 6 times per day.

Drug Facts (continued)

Other Information: Store at room temperature. Avoid direct sunlight. Do not use if tamper evident packaging has been breached or is missing. See bottom of this jar for lot number and expiry date.

Inactive ingredients: Benzyl Alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine and Vitamin E Acetate.



Questions and comments? Call 1-833-663-2933

129+/-2mm



Package Label for the Jar



ANORECTAL HEMORRHOIDAL CREAM WITH LIDOCAINE 5%

lidocaine 5% cream cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55629-019 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.05 g in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARBOMER 940 (UNII: 4Q93RCW27E)		
CHOLESTEROL (UNII: 97C5T2UQ7J)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 903K93S3TK)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55629-019- 04	113 g in 1 TUBE; Type 0: Not a Combination Product	09/25/2024			
2	NDC:55629-019- 05	142 g in 1 JAR; Type 0: Not a Combination Product	09/25/2024			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M	09/25/2024			

Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Revised: 9/2024 ONE2ZEE LIMITED LIABILITY COMPANY