

HEMORRHOID ANESTHETIC- mineral oil, petrolatum, phenylephrine hcl ointment

Universal Distribution Center LLC

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.

Hemorrhoid Anesthetic Ointment

Active Ingredients

Mineral Oil 14%

Petrolatum 74.9%

Phenylephrine HCL 0.25%

Purpose

Protectant

Protectant

Vasoconstrictor

Uses

- For the temporary relief of local anorectal burning and discomfort associated with hemmorrhoids, anorectal disorders, inflamed hemorrhoidal tissues or piles.

Warnings

For external use only.

- **Stop use and ask a doctor** if condition worsens, or if symptoms persist for more than 7 days or clean-up and occur again within a few days.
- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly.
- Certain persons can develop allergic reactions to ingredients in this product.
- If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor.
- If you are pregnant, do not use this product without first consulting a doctor.

Keep out of reach of children.

If ingested seek medical attention immediately or contact a Poison Control Center right away.

Directions

- Cleanse the affected area with mild soap and warm water, rinse thoroughly.
- Dry by patting or blotting with toilet tissue or soft cloth before applying this product.
- Cover the entire affected area with a thin layer 1 to 3 times daily.
- Children under 12 years of age need to consult a doctor before using this product.

Other Information

- Store at 20°C to 25°C (68°F to 77°F)
- Lot No. & Exp. Date: see crimp of tube.

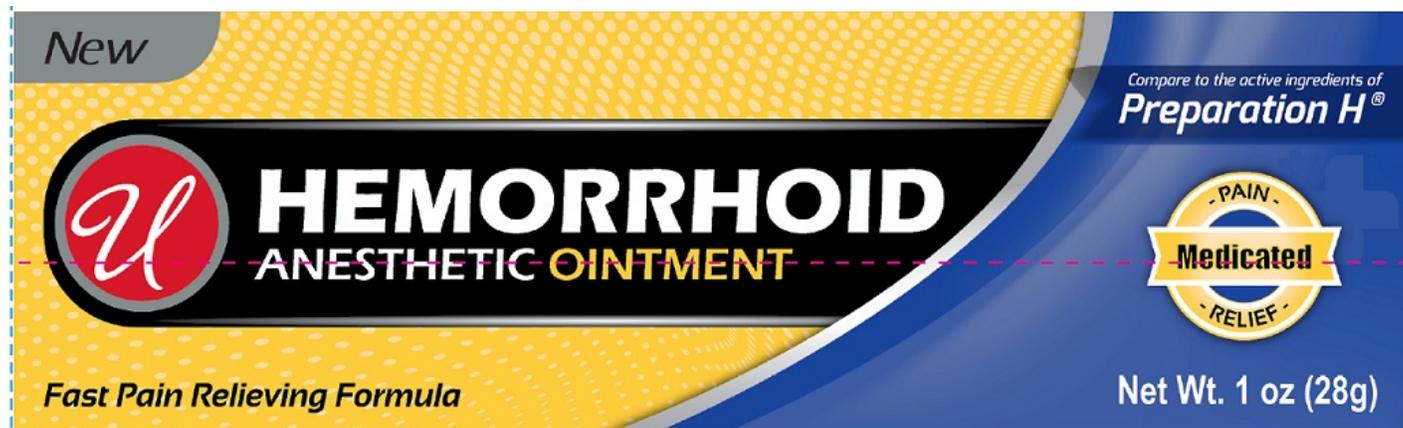
Inactive Ingredients

benzoic acid, butylated hydroxyanisole, glycerin, lanolin, lanolin alcohol, methylparaben, paraffin, propylparaben, tocopherol acetate, yellow wax.

PRINCIPAL DISPLAY PANEL

Hemorrhoid Anesthetic Ointment

NET WT. 1 OZ. (28 g)



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This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the trademark Preparation H®. Item#86077 Made in India

Distributed By: Universal Distribution Center, 96 Distribution Boulevard, Edison, NJ 08817 www.universalbrandsusa.com

HEMORRHOID ANESTHETIC

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	0.14 g in 1 g

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.749 g in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.0025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-057-01	1 in 1 CARTON	12/09/2020	
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	12/09/2020	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-057)