

HEMORRHOID ANESTHETIC- mineral oil, petrolatum, phenylephrine hcl ointment

Universal Distribution Center LLC

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)



Drug Facts

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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:52000-057-02	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 Drug	M016	12/09/2020	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Savvy Care & Cosmetics Pvt. Ltd. (915039748)

Establishment

Name	Address	ID/FEI	Business Operations
Savvy Care & Cosmetics Pvt. Ltd.		915039748	manufacture(52000-057)

Revised: 5/2024

Universal Distribution Center LLC