

HEMORRHOID ANESTHETIC- mineral oil, petrolatum, phenylephrine hcl ointment
Anicare Pharmaceuticals Pvt. Ltd

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 hemorrhoids, 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)


New

Compare to the active ingredients of
Preparation H®



HEMORRHOID

ANESTHETIC OINTMENT



Fast Pain Relieving Formula Net Wt. 1 oz (28g)

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:47046-153
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: 8SKN0B0MM)
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
GLYCERIN (UNII: PDC6A3C0OX)
LANOLIN (UNII: 7EV65EAW6H)
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)
METHYL PARABEN (UNII: A2I8C7HI9T)
PARAFFIN (UNII: I9O0E3H2ZE)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
YELLOW WAX (UNII: 2ZA36H0S2V)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-153-02	1 in 1 CARTON	12/09/2020	
1	NDC:47046-153-01	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 - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Revised: 12/2020

Anicare Pharmaceuticals Pvt. Ltd