BUDPAK HEMORRHOID ANESTHETIC- mineral oil, petrolatum, phenylephrine hcl ointment
Budpak Inc.

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.

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

Inactive Ingredients

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohol, methylparaben, mineral oil, paraffin, propylparaben, shark liver oil, thyme oil, tocopherol acetate, yellow wax, purified water.

PRINCIPAL DISPLAY PANEL

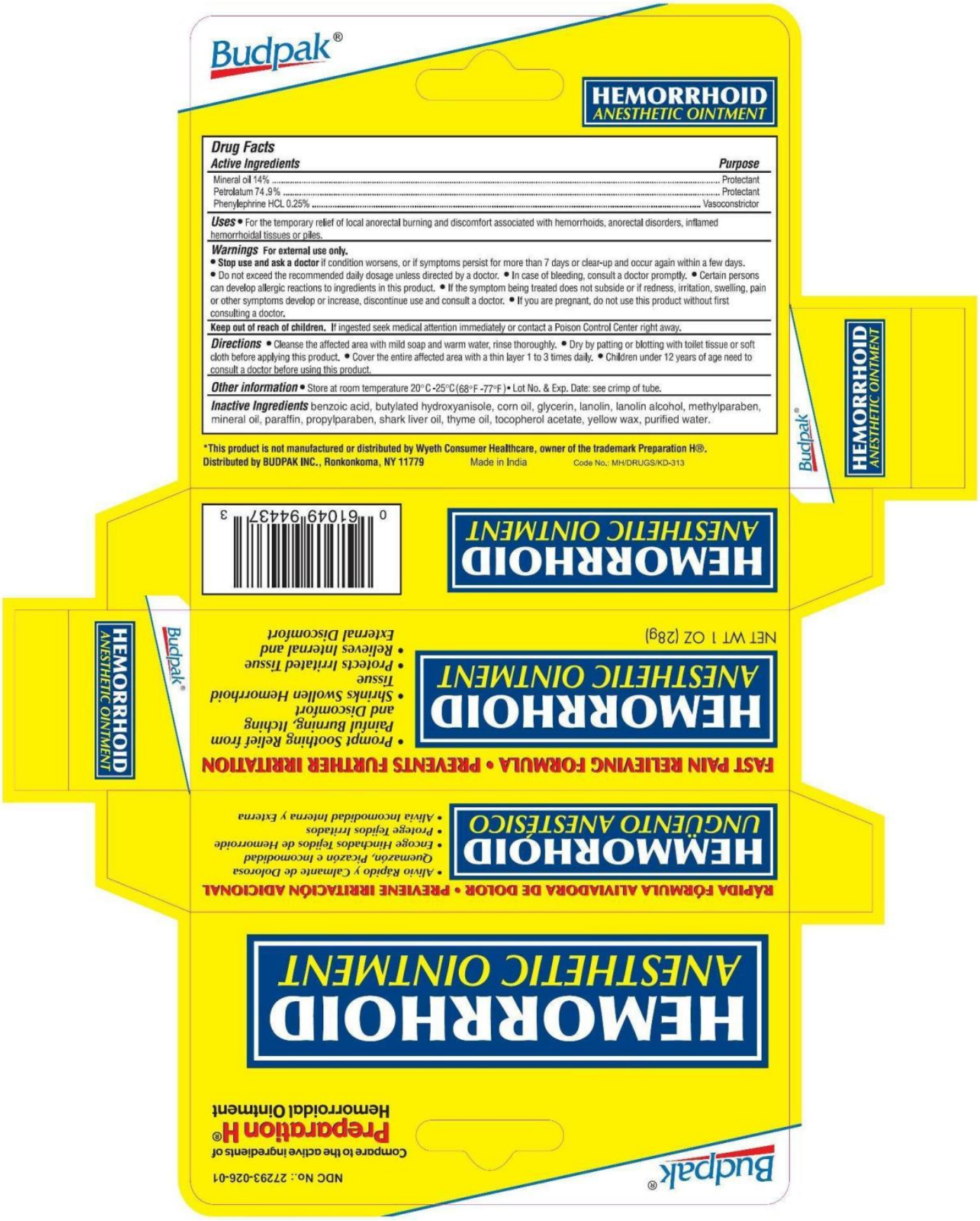
Budpak Hemorrhoid Anesthetic Ointment

Mineral Oil 14%

Petrolatum 74.9%

Phenylephrine HCL 0.25%

NET WT 1 OZ (28 g)



BUDPAK HEMORRHOID ANESTHETIC

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-026
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)	
CORN OIL (UNII: 8470G57WFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHARK LIVER OIL (UNII: 4B24275HEU)	
THYME OIL (UNII: 2UK410MY6B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-026-01	1 in 1 BOX		
1	NDC:27293-026-28	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/10/2013	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-026)

Revised: 10/2013 Budpak Inc.