HEMORRHOIDAL ANESTHETIC- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, and petrolatum cream
Purity Products

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.

Hemorrhoidal Cream
Anesthetic

Drug Facts

Active Ingredients	Purposes
Glycerin 14.4%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local Anesthetic
White petrolatum 15%	Protectant

Uses

- For temporary relief of pain, soreness and burning
- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoidal tissue and relieves burning
- Temporarily provides a coating for relief of anorectal discomforts
- Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For external use only

Ask a doctor before use if you have

- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes
- Difficulty urinating due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking a prescription drug for high blood pressure or depression

When using this product

- Do not exceed the recommended daily dosage unless directed by a doctor
- Do not put into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- Bleeding occurs the condition worsens or does not improve within 7 days
- An allergic reaction develops
- The symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or soft cloth before applying the cream
- When first opening the tube, remove the foil seal
- Apply externally or in the lower portion of the anal canal only
- Apply externally to the affected area up to 4 times daily, especially at night, in the morning, or after each bowel movement
- For application in the lower anal canal; remove the cover from the dispensing cap. Attach the dispensing cap to the tube. Lubricate the dispensing cap well, then gently insert the dispensing cap partway into the anus.
- Thoroughly cleanse the dispensing cap after each use, and replace the cover
- Children under 12 years: ask a doctor

Other Information

- Store at 15 to 30°C (59 to 86°F)

Inactive Ingredient

Aloe barbadensis leaf extract, anhydrous citric acid, butylated hydroxyanisole, cetyl alcohol, edetate disodium, glyceryl monostearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, sodium carboxymethyl cellulose, steareth-2, steareth-20, stearyl alcohol, vitamin E acetate, xanthan gum

Questions or comments?

To Reorder Call: 1-800-281-7781, Customer Care: 1-888-769-7873 or www.purityproducts.com

PRINCIPAL DISPLAY PANEL - 25.5 G Tube Carton

NET WT.
0.9 OZ (25.5 G)

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RAPID
SOOTHING
Relief & Comfort

MAXIMUM STRENGTH FOR PAINFUL
BURNING, ITCHING, & DISCOMFORT.

ANESTHETIC
HEMORRHOIDAL
CREAM

with
SOOTHING
ALOE

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NDC 71003-001-01

RECTIFY™ HAS YOUR BACK.

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PL31950B
V01

- Relieves External Discomfort
- Heals & Protects Irritated Tissue
- Shrinks swollen hemorrhoidal tissue

Rectify™
ANESTHETIC
HEMORRHOIDAL CREAM

NET WT.
0.9 OZ (25.5 G)

RAPID SOOTHING
Relief & Comfort

MAXIMUM STRENGTH FOR PAINFUL BURNING, ITCHING, & DISCOMFORT.

ANESTHETIC
HEMORRHOIDAL
CREAM

Manufactured for
Rectify™
A division of
Purity Products®
200 Terminal Drive Plainview, NY 11803

0 40232 48294 6

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RECTIFY™ HAS YOUR BACK.

Rectify™

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71003-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WV9CM0O67Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71003-001-01	1 in 1 CARTON	10/20/2016	
1		25 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	10/20/2016	

Labeler - Purity Products (807859509)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex		062808196	MANUFACTURE(71003-001)

Revised: 10/2016 Purity Products