

NATUREPLEX HEMORRHOIDAL- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, and petrolatum cream

Natureplex 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.

**Natureplex™
Hemorrhoidal**

Drug Facts

<i>Active ingredients</i>	<i>Purposes</i>
Glycerin 14.4%	Protectant
Petrolatum 15%	Protectant
Phenylephrine hydrochloride 0.25%	Vasoconstrictor
Pramoxine hydrochloride 1%	Local Anesthetic

Uses

- temporarily relieves pain, soreness, and burning
- helps relieve local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- 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: 800-222-1222.

Directions

Adults:

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

Other information

- store at 15 to 30°C (59 to 86°F)
- close cap tightly after use
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, BHA, cetyl alcohol, citric acid, disodium EDTA, glyceryl stearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, sodium carboxymethyl cellulose, steareth-2, steareth-20, stearyl alcohol, tocopheryl (vitamin E) acetate, xanthan gum

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 26 g Tube Box

NDC 67234-025-01

Includes

Dispensing

Cap

Natureplex™

Anesthetic

HEMORRHOIDAL

Cream

With Soothing Aloe

NET WT. 0.9 Oz.(26g)

Maximum Strength Pain Relief

* Compare active ingredients to Preparation H® Cream

Natureplex®

Anesthetic HEMORRHOIDAL Cream

With Soothing Aloe

Helps Heal Irritated Tissue

Maximum Strength Pain Relief



Fast Relief!

- Rapid, Soothing Pain Relief From Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves External Discomfort



3065B
V05

Includes Dispensing Cap



NDC 67234-025-01

Anesthetic HEMORRHOIDAL Cream With Soothing Aloe

Natureplex®

Anesthetic HEMORRHOIDAL Cream

With Soothing Aloe

NET WT. 0.9 Oz. (26g)

Maximum Strength Pain Relief

Natureplex®

Anesthetic HEMORRHOIDAL Cream

With Soothing Aloe

*This product is not manufactured by or distributed by Pfizer, Inc., the distributor of Preparation H®.



NATUREPLEX, Olive Branch, MS 38654



<p>Drug Facts (continued)</p> <p>Purposes Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 800-222-1222.</p> <p>Directions Adults: • When practical, cleanse a rected area by patting or blotting with a damp cloth before applying cream. • When first opening tube, remove to it seal • apply externally or in lower portion of anal canal only. • apply externally after each bowel movement. • when first opening tube, especially at night, in the morning, or after each bowel movement. • For application in lower anal canal, remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into anus. • Thoroughly cleanse dispensing cap after each use, and replace cover. • Children under 12 years: ask a doctor.</p> <p>Other information • store at 15 to 30°C (59 to 86°F) • close cap tightly after use • Tamper Evident: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.</p> <p>Inactive ingredients aloe barbadensis leaf juice, BHA, cetyl alcohol, citric acid, disodium EDTA, glyceryl stearate, lauric acid, methylparaben, mineral oil, parabens, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, sodium carboxymethyl cellulose, steareth-2, steareth-20, stearyl alcohol, tocopherol (Vitamin E acetate), xanthan gum.</p> <p>Questions or comments? 866-323-0107 or www.natureplex.com</p>	<p>Drug Facts</p> <p>Active ingredients Glycerin 14.5%, Paralamin 1.5%, Phenylephrine hydrochloride 0.25%, Pronated Vasoconstrictor Local Anesthetic</p> <p>Uses • temporarily relieves pain, soreness, and burning • helps relieve local itching and discomfort associated with hemorrhoids • temporarily shrinks hemorrhoidal tissue • temporarily provides a coating for relief of anorectal discomfort • temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful</p> <p>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.</p>
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Natureplex®

Anesthetic HEMORRHOIDAL Cream With Soothing Aloe

NATUREPLEX HEMORRHOIDAL

glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, and petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.144 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.0025 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	0.1 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.15 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67234-025-01	1 in 1 BOX	03/01/2014	
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	03/01/2014	

Labeler - Natureplex LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-025)

Revised: 12/2017

Natureplex LLC