

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

Natureplex™
Hemorrhoidal

Drug Facts

| Active ingredients | Purposes |
|-----------------------------------|---------------------|
| 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

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: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X) | GLYCERIN | 0.144 mg in 1 g |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV) | 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 (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: WW9CM0067Z) | |
| 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: 2KR89I4H1Y) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| WATER (UNII: 059QF0KO0R) | |
| 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 drug | M015 | 03/01/2014 | |

Labeler - Natureplex LLC (062808196)

Establishment

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

Revised: 12/2024

Natureplex LLC