

PREPARATION H RAPID RELIEF- glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream

GlaxoSmithKline Consumer Healthcare Holdings (US) 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.

Drug Facts

Active Ingredients

Glycerin 14.4%

Lidocaine 5%

Phenylephrine HCl 0.25%

White petrolatum 15%

Purposes

Protectant

Local anesthetic

Vasoconstrictor

Protectant

Uses

- for temporary relief of pain, soreness and burning
- helps relieve the 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 in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are presently 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
- 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 a soft cloth before applying this cream.
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- children under 12 years of age: ask a doctor

Other information

store at 20-25°C (68-77°F)

Inactive ingredients

aloe barbadensis leaf extract, anhydrous citric acid, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid monohydrate, dexpanthenol, edetate disodium, glyceryl monostearate, methylparaben, mineral oil, polyoxyl lauryl ether, polyoxyl stearyl ether, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, stearyl alcohol, tocopherols excipient, vitamin E acetate, xanthan gum

Questions or comments?

Call weekdays 9 AM to 5 PM EST at **1-800-99PrepH** or **1-800-997-7374**

PRINCIPAL DISPLAY PANEL

PREPARATION H®

New Benefit

Now Reduces Swelling
See new label

RAPID RELIEF
WITH
LIDOCAINE

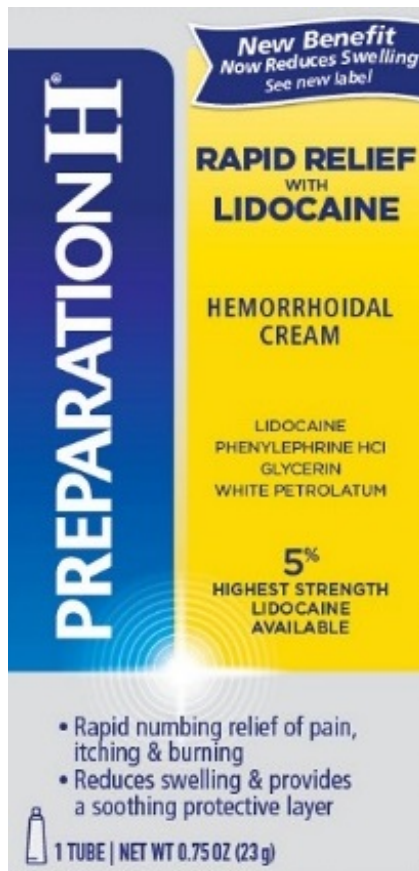
HEMORRHOIDAL CREAM

LIDOCAINE
PHENYLEPHRINE HCl
GLYCERIN
WHITE PETROLATUM

**5%
HIGHEST STRENGTH
LIDOCAINE
AVAILABLE**

- Rapid numbing relief of pain, itching & burning
- Reduces swelling & provides a soothing protective layer

1 TUBE | NET WT 0.75 OZ (23 g)



PREPARATION H RAPID RELIEF

glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0573-2843

| | |
|--------------------------------|---------|
| 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 |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 50 mg in 1 g |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 150 mg in 1 g |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 2.5 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| DEXPANTHENOL (UNII: 1O6C93RI7Z) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| LAURETH-23 (UNII: N72LMW566G) | |
| STEARETH-2 (UNII: V56DFE46J5) | |
| STEARETH-20 (UNII: L0Q8IK9E08) | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0573-2843-01 | 1 in 1 CARTON | 11/01/2018 | |
| 1 | | 23 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:0573-2843-10 | 1 in 1 CARTON | 11/01/2018 | |

2

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 | 11/01/2018 | |

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|---|
| PF Consumer Healthcare Canada ULC | | 203812479 | ANALYSIS(0573-2843) , LABEL(0573-2843) , MANUFACTURE(0573-2843) , PACK(0573-2843) |

Revised: 1/2023

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC