

PREPARATION H RAPID RELIEF- glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream
Haleon US Holdings LLC

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**

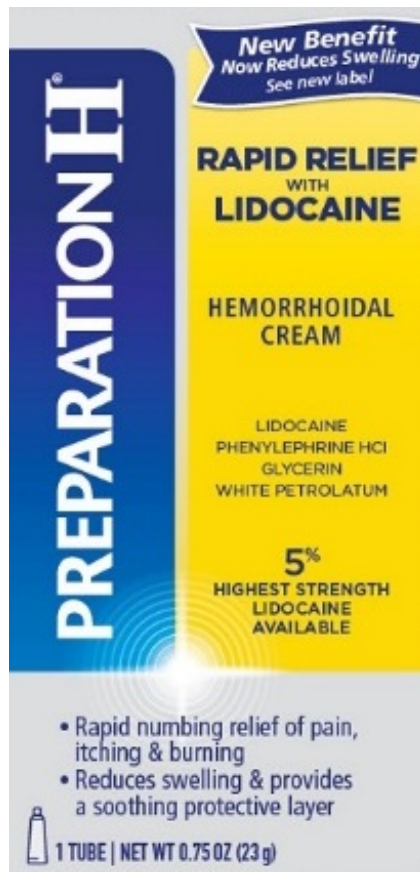
LIDOCAINE
PHENYLEPHRINE HCl
GLYCERIN

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
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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
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

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	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M015	11/01/2018	

Labeler - Haleon US Holdings LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Pf Soins De Sant? Sri		203812479	analysis(0573-2843) , label(0573-2843) , manufacture(0573-2843) , pack(0573-2843)

Revised: 2/2024

Haleon US Holdings LLC