

PREPARATION H COOLING GEL- phenylephrine hcl, witch hazel gel
Haleon US Holdings LLC

Drug Facts

Active ingredients

Phenylephrine HCl 0.25%

Witch hazel 50.0%

Purposes

Vasoconstrictor

Astringent

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas

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 this product 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

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 gel.
- when first opening the tube, puncture foil seal with top end of cap
- 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 juice, edetate disodium, hydroxyethyl cellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, sulisobenzone, vitamin E acetate

Questions or comments?

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

Additional information

Do Not Use if tube seal under cap embossed with “H” is broken or missing.

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

For most recent product information, visit www.preparationh.com

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PRINCIPAL DISPLAY PANEL

PREPARATION H

HEMORRHOIDAL

COOLING GEL

Fast Cooling

Relief

- Clear, Non-Greasy Formula with No Unpleasant Scent
- Prompt, Cooling Relief from Painful Burning & Itching
- Shrinks Swollen Hemorrhoidal Tissue
- Relieves External Discomfort

1 TUBE | NET WT 1.8 OZ (51 g)

PAA162794 Front Carton

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2840	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g	
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)		WTCH HAZEL	500 mg in 1 g	
Inactive Ingredients				
Ingredient Name				Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136Y38GY5)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SULISOBENZONE (UNII: 1W6L629B4K)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2840-10	1 in 1 CARTON	01/01/2004	
1		26 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0573-2840-20	1 in 1 CARTON	01/01/2004	
2		51 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	01/01/2004		

Labeler - Haleon US Holdings LLC (079944263)