PREPARATION H COOLING GEL- phenylephrine hcl, witch hazel gel
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

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

Made In Canada

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

PRINCIPAL DISPLAY PANEL

PREPARATION H

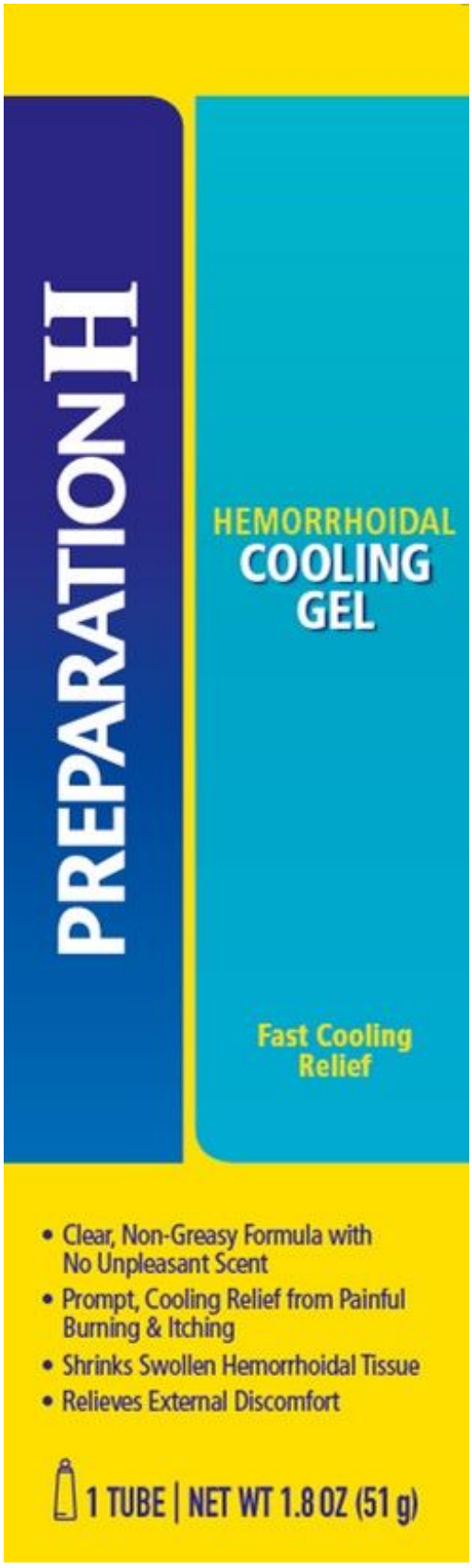
HEMORRHOIDAL
COOLING
GEL

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



PREPARATION H COOLING GEL

phenylephrine hcl, witch hazel gel

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) (WITCH HAZEL - UNII:101I4J0U34)	WITCH HAZEL	500 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE (140 MPA.S 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 final	part346	01/01/2004	

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

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	MANUFACTURE(0573-2840)

Revised: 12/2022 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC