

HEB HEMORRHOIDAL COOLING GEL- witch hazel and phenylephrine hydrochloride cream
HEB

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.

HEB HEMORRHOIDAL COOLING GEL
TOPICAL

Drug Facts

| <i>Active ingredients</i> | <i>Purpose</i> |
|---|-----------------------|
| Hamamelis virginiana (witch hazel) 50% | Astringent |
| Phenylephrine hydrochloride 0.25% | Vasoconstrictor |

Uses

- temporarily relieves anorectal itching and discomfort associated with hemorrhoids or anorectal disorders
- temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas
- temporary relief of burning

Warnings

For external use only.

Do not use this product

- if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

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 recommended daily dosage unless directed by a doctor
- do not put into rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- bleeding occurs

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 gel
 - apply externally to affected area up to 4 times daily or after each bowel movement
- **Children under 12 years old:** Ask a doctor

Other information

- Store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

Aloe barbadensis leaf juice, benzophenone-4, disodium EDTA, hydroxyethylcellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

Questions or comments?

866-323-0107

PRINCIPAL DISPLAY PANEL - 26 g Tube Carton

Compare to Preparation H[®] Hemorrhoidal Cooling Gel active ingredients*

NDC 37808-993-24

H-E-B[®]

Hemorrhoidal Cooling Gel

Hamamelis Virginiana (Witch Hazel) / Astringent • Phenylephrine Hydrochloride / Vasoconstrictor

Hemorrhoid Symptom Relief

With Soothing Aloe

- Clear, Non-Greasy Formula with a Pleasant Scent
- Prompt Cooling Relief from Painful Burning and Itching
- Shrinks Swollen Hemorrhoidal Tissue • Relieves External Discomfort

NET WT 0.9 OZ (26 g)



HEB HEMORRHOIDAL COOLING GEL

witch hazel and phenylephrine hydrochloride cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-993 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|------------------|
| WITCH HAZEL (UNII: 10 1I4J0 U34) (WITCH HAZEL - UNII:10 1I4J0 U34) | WITCH HAZEL | 0.5 mg in 1 g |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59 TNSJ) (PHENYLEPHRINE - UNII:1WS29 7W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 0.0025 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |
| SULISOBENZONE (UNII: 1W6 L6 29 B4K) | |
| EDETATE DISODIUM (UNII: 7FLD9 1C8 6K) | |

HYDROXYETHYL CELLULOSE (100 MPAS AT 2 %) (UNII: R33S7TK2EP)

METHYL PARABEN (UNII: A2I8C7HI9T)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PROPYL PARABEN (UNII: Z8IX2SC1OH)

WATER (UNII: 059QF0K00R)

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:37808-993-24 | 1 in 1 CARTON | 10/18/2018 | |
| 1 | | 26 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 | 10/18/2018 | |

Labeler - HEB (007924756)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| Natureplex LLC | | 062808196 | MANUFACTURE(37808-993) |

Revised: 10/2018

HEB