

HEB HEMORRHOIDAL- mineral oil, petrolatum, and phenylephrine hydrochloride cream H-E-B

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 Ointment

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Mineral Oil 14%	Protectant
Petrolatum 74.9%	Protectant
Phenylephrine hydrochloride 0.25%	Vasoconstrictor

Uses

- For the temporary relief of anorectal itching and discomfort associated with hemorrhoids.
- Temporarily reduces swelling associated with irritation in hemorrhoids and other anorectal disorders
- Temporarily shrinks hemorrhoidal tissue
- Temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues
- Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For external and/or intrarectal 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 the recommended daily dosage unless directed by a doctor

Stop use and ask a physician if

- bleeding occurs
- condition worsens or does not improve within 7 days
- introduction of applicator into rectum causes additional pain

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 the affected area by patting or blotting with an appropriate cleansing pad. Gently dry by patting or blotting with a tissue or a soft cloth before application of this product
- apply externally to the affected area up to 4 times daily
- intrarectal use: remove cover from applicator, attach applicator to tube, lubricate applicator well and

gently insert applicator into the rectum, thoroughly cleanse applicator after each use and replace cover

- Children under 12 years of age: consult a physician

Other information

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

Inactive ingredients

Benzoic acid, cera alba (bees wax), glycerin, lanolin, lanolin alcohol, methylparaben, paraffin, propylparaben, purified water, thymus vulgaris (thyme) oil, tocopherol (vitamin E) acetate

Questions or comments?

866-323-0107

PRINCIPAL DISPLAY PANEL - 56.7 g Tube Carton

Compare to Preparation H[®] Ointment active ingredients*

H-E-B[®]

NDC 37808-991-24

Hemorrhoidal Ointment

Mineral Oil / Petrolatum / Protectant

Phenylephrine Hydrochloride / Vasoconstrictor

Includes

Dispensing

Cap

Hemorrhoid Symptom Relief

- Helps Relieve Pain & Itching
- Lubricating Coating Protects Irritated Tissue

NET WT 2.0 OZ (56.7 g)



HEB HEMORRHOIDAL

mineral oil, petrolatum, and phenylephrine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-991
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	14 g in 100 g
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	74.9 g in 100 g
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Benzoic Acid (UNII: 8SKN0B0MIM)	
White Wax (UNII: 7G1J5DA97F)	

Glycerin (UNII: PDC6A3C0OX)	
Lanolin (UNII: 7EV65EAW6H)	
Lanolin Alcohols (UNII: 884C3FA9HE)	
Methylparaben (UNII: A2I8C7HI9T)	
Paraffin (UNII: I9O0E3H2ZE)	
Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
Thyme Oil (UNII: 2UK410MY6B)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-991-24	1 in 1 CARTON	10/23/2018	
1		56.7 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	10/23/2018	

Labeler - H-E-B (007924756)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(37808-991)

Revised: 10/2018

H-E-B