HEMORRHOIDAL- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride and petrolatum 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 Cream Drug Facts

Active ingredients

Glycerin 14.4%
Phenylephrine HCl 0.25%
Pramoxine HCl 1%
White petrolatum 15%

Purpose

Protectant

Vasoconstrictor

Local anesthetic

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
- trouble urinating due to an enlarged 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 cream.
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover
- 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, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl monostearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, vitamin E, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredients of Preparation H® Cream

HEMORRHOIDALCREAM

Maximum Strength Pain Relief

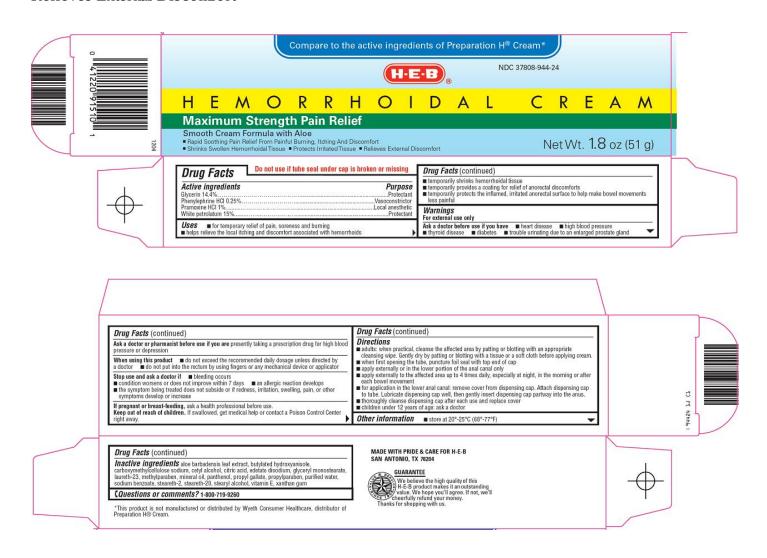
Smooth Cream Formula with Aloe

Rapid Soothing Pain Relief From Painful Burning, Itching And Discomfort

Shrinks Swollen Hemorrhoidal Tissue

Protects Irritated Tissue

Relieves External Discomfort



HEMORRHOIDAL

GLYCERIN (GLYCERIN)

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:37808-944
Route of Administration	TOPICAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

GLYCERIN

14.4 g in 100 g

PHENYLEPHRINE HYDRO CHLO RIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PRAMO XINE HYDRO CHLO RIDE (PRAMO XINE)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
PETROLATUM (PETROLATUM)	PETROLATUM	15 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF	
BUTYLATED HYDRO XYANISOLE	
CARBO XYMETHYLCELLULO SE SO DIUM	
CETYL ALCOHOL	
CITRIC ACID MO NO HYDRATE	
EDETATE DISO DIUM	
GLYCERYL MONOSTEARATE	
LAURETH-23	
METHYLPARABEN	
MINERAL O IL	
PANTHENOL	
PROPYL GALLATE	
PROPYLPARABEN	
WATER	
SODIUM BENZOATE	
STEARETH-2	
STEARETH-20	
STEARYL ALCOHOL	
.ALPHATO CO PHERO L	
XANTHAN GUM	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37808-944-24	1 in 1 CARTON		
1	51 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	10/25/2012	

Revised: 11/2012 HE B