HEMORRHOIDAL- glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream Meijer Distribution Inc

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.

Meijer Distribution, Inc. 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 Preparation H $\ensuremath{\mathbb{R}}$ Cream active ingredients

hemorrhoidal cream

Glycerin | Phenylephrine HCl
Pramoxine HCl | White Petrolatum
Maximum Strength Pain Relief
WITH ALOE & VITAMIN E
Soothes Itching, Burning & Discomfort
Shrinks Swollen Hemorrhoidal Tissue
Protects Irritated Tissue
NET WT 1.8 OZ (51g)



NDC 41250-944-24 Compare to Preparation H[®]Cream

active ingredients

hemorrhoidal

Glycerin | Phenylephrine HCl

Pramoxine HCl | White Petrolatum

Maximum Strength Pain Relief

cream

WITH ALOE &

Soothes Itching,

Shrinks Swollen

Burning & Discomfort

Hemorrhoidal Tissue

Protects Irritated Tissue

VITAMIN E

meijer

Compare to Preparation H® Cream active ingredents* crea WITH ALOE & VITAMIN

Soothes Itching, Burning & Discomfort | Maximum Strength Pain Relief Glycerin | Phenylephrine HCl |

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51

70

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Drug Facts (continued)

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Ouestions or comments? 1-800-719-9260

This product is not manufactured or distributed by Wyeth LLC, owner of the registered trademark Preparation H.

DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING

DIST, BY MEIJER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544 www.meijer.com



PID 361845



94424 6E C3

NET WT 1.8 OZ (51 g)





HEMORRHOIDAL

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-944
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g	
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB867L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
LAURETH-23 (UNII: N72LMW566G)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
MINERAL OIL (UNII: T5L8T28FGP)		
PANTHENOL (UNII: WV9CM0O67Z)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
STEARETH-2 (UNII: V56DFE46J5)		
STEARETH-20 (UNII: L0Q8IK9E08)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
.ALPHATO COPHERO L (UNII: H4N855PNZ1)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

I	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41250-944-24	1 in 1 CARTON	02/06/2008			
1		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	02/06/2008	

Labeler - Meijer Distribution Inc (006959555)

Revised: 3/2019 Meijer Distribution Inc