HEMORRHOIDAL- glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream CVS Pharmacy

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.

CVS Pharmacy, 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
- an allergic reaction develops
- condition worsens or does not improve within 7 days
- 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. (1-800-222-1222)

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

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 in Preparation $H^{\ensuremath{\mathbb{R}}}$ Cream

Hemorrhoidal Cream

SMOOTH CREAM FORMULA with ALOE

Rapid, soothing pain relief from painful burning, itching & discomfort

Protects irritated tissue

Relieves external discomfort Shrinks swollen hemorrhoidal tissue with Aloe Package Contains One Tube NET WT 1.8 OZ (51 g)





	ramoxine hcl, white petrolatum	i cicain					
Product Information							
Product T ype	HUMAN OTC DRUG	Item Code	n Code (Source) NDC		DC:59779-944		
Route of Administration	TOPICAL						
Active Ingredient/Active	Moiety						
]	Ingredient Name		Basis of Strength		Strength		
GLYCERIN (UNII: PDC6A3C0OX)	GLYCERIN					
PHENYLEPHRINE HYDRO CHLC UNII:1WS297W6 MV)	LEPHRINE -	PHENYLEPHRINE HYDROCHLORIDE		0.25 g in 100 g			
PRAMOXINE HYDROCHLORID UNII:068X84E056)	NE -	PRAMOXINE HYDROCHLORIDE		1 g in 100 g			
PETROLATUM (UNII: 4T6H12BN	19U) (PETROLATUM - UNII:4T6H12	BN9U)	PETROLATUM		15 g in 100 g		
Ingredient Name ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)							
-	Ingredient Name	e			Strength		
BUTYLATED HYDRO XYANISO							
	SE SODIUM, UNSPECIFIED FORM	I (UNII: K679OB	\$311)				
CETYL ALCOHOL (UNII: 936JS							
CITRIC ACID MONOHYDRATE EDETATE DISODIUM (UNII: 7FL)							
GLYCERYL MONOSTEARATE							
LAURETH-23 (UNII: N72LMW566							
METHYLPARABEN (UNII: A218C							
•							
MINERAL OIL (UNII: T5L8T28F0	JI)						
PANTHENOL (UNII: WV9CM006	57Z)						
PANTHENOL (UNII: WV9CM0O6 PROPYL GALLATE (UNII: 8D4S	57Z) NN7V92)						
PANTHENOL (UNII: WV9CM0O6 PROPYL GALLATE (UNII: 8D4S PROPYLPARABEN (UNII: Z8IX2:	57Z) NN7V92)						
PANTHENOL (UNII: WV9CM0O6 PROPYL GALLATE (UNII: 8D4S PROPYLPARABEN (UNII: Z8IX23 WATER (UNII: 059QF0KO0R)	57Z) NN7V92) SC1OH)						
PANTHENOL (UNII: WV9CM0O6 PROPYL GALLATE (UNII: 8D4S PROPYLPARABEN (UNII: Z8IX2: WATER (UNII: 059QF0KO0R) SODIUM BENZOATE (UNII: 0J2:	57Z) NN7V92) SC10H) 45FE5EU)						
PANTHENOL (UNII: WV9CM006 PROPYL GALLATE (UNII: 8D4S PROPYLPARABEN (UNII: 28IX23 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J2 STEARETH-2 (UNII: V56DFE46J3	57Z) NN7V92) SC10H) 45FE5EU) 5)						
PANTHENOL (UNII: WV9CM006 PROPYL GALLATE (UNII: 8D4S PROPYLPARABEN (UNII: 28IX2: WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J2: STEARETH-2 (UNII: V56DFE46J5 STEARETH-20 (UNII: L0Q8IK9E	57Z) NN7V92) SC10H) 45FE5EU) 5) 08)						
MINERAL OIL (UNII: T5L8T28FC PANTHENOL (UNII: WV9CM006 PROPYL GALLATE (UNII: 8D4S PROPYLPARABEN (UNII: 28IX23 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J24 STEARETH-2 (UNII: V56DFE46J5 STEARETH-20 (UNII: L0Q8IK9E STEARYL ALCOHOL (UNII: 2KF .ALPHATOCOPHEROL (UNII: 1	57Z) NN7V92) SC10H) 45FE5EU) 5) 08) R8914H1Y)						

Product Character	ristics							
Color	WHITE		Score					
Shape			Size					
Flavor			Imprint Code					
Contains								
Packaging								
# Item Code		Package Description		Marketing Start Date	Marketing E	nd Date		
1 NDC:59779-944-24	1 in 1 CARTON			02/06/2008				
1	51 g in 1 TUBI	E; Type 0: Not a Combinatio	n Product					
Marketing Information								
Marketing Category	Applicat	ion Number or Monogra	ph Citation	Marketing Start Date	Marketing E	and Date		
OTC monograph final	part346			02/06/2008				

Labeler - CVS Pharmacy (062312574)

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