

CVS HEMORRHOIDAL- glycerin phenylephrine hci pramoxine hci white petrolatum cream
CVS Pharmacy, 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.

CVS Hemorrhoidal Cream 1oz (with applicator) (48175, 2018)

Active Ingredients	Purpose
Glycerin 14.4%.....	Protectant
Phenylephrine HCl 0.25%.....	Vasoconstrictor
Pramoxine HCl 1%.....	Local anesthetic
White Petrolatum 15%.....	Protectant

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
- Difficulty in urination due to enlargement of the 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 rectum by using fingers or any mechanical device or applicator

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.
- 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 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 hydroxytoluene, cetosteryl alcohol, cetyl esters, cetyl palmitate, distilled water, glycerol monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, sodium citrate hydrate, stearic acid, tocopherol acetate

DISTRIBUTED BY:

CVS PHARMACY, INC.

ONE CVS DRIVE

WOONSOCKET, RI 02895 USA



CVS HEMORRHOIDAL			
glycerin phenylephrine hci pramoxine hci white petrolatum cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-752
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 HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	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: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-752-28	1 in 1 BOX	09/12/2016	
1		1 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	01/17/2014	

Labeler - CVS Pharmacy, Inc. (062312574)