

CVS HEALTH HEMORRHOIDAL CREAM- glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

FRONT PHARMACEUTICAL PLC

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 Health Hemorrhoidal Cream, 28g

Active ingredients

Glycerin 14.4%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

White petrolatum 15%

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 provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed irritated anorectal surface to help make bowel movements less painful
- temporarily shrinks hemorrhoidal tissue

Warnings

For external use only.

When using this product •do not put this product into the rectum by using fingers or any mechanical device or applicator •do not exceed recommended daily dosage unless directed by a doctor

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

Stop use and ask a doctor if

- bleeding occurs •condition worsens or does not improve within 7 days
- if the symptoms being treated do not subside or if redness, irritation, swelling, pain or other symptoms develop or increase. Some people can develop allergic reactions to ingredients in this product.

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 with mild soap and water and rinse thoroughly.
Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.

- apply externally to the affected area up to 4 times daily, especially at night or in the morning or after each bowel movement.

Children under 12 years of age: consult a doctor.

Other information store at room temperature 68° - 77° F (20° - 25° C)

Inactive ingredients aloe barbadensis leaf extract, carboxymethylcellulose sodium, cetyl alcohol, glyceryl monostearate, methylparaben, paraffin, propylene glycol, propylparaben, stearic acid, tween 80, water, xanthan gum

Questions? 1-800-639-3803 Weekdays 9 AM to 4 PM EST



CVS HEALTH HEMORRHOIDAL CREAM

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69571-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	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)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69571-010-28	1 in 1 BOX	02/12/2018	
1		28 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	02/12/2018	

Labeler - FRONT PHARMACEUTICAL PLC (530897792)

Establishment

Name	Address	ID/FEI	Business Operations
FRONT PHARMACEUTICAL PLC		530897792	manufacture(69571-010)

Revised: 12/2019

FRONT PHARMACEUTICAL PLC