FAMILY WELLNESS- glycerin, phenylephrine hcl, pramoxine hcl, petrolatum cream FRONT PHARMACEUTICAL PLC

Active ingredients (in each gram)

Glycerin 14.4%

Phenylephrine HCL 0.25%

Pramoxine HCL 1%

White petrolatum 15%

Purpose

Protectant

Vasoconstrictor

Local anesthetic

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

When using this product

Ask a doctor before use if you have

•heart disease •high blood pressure •thyroid disease •diabetes

•trouble urinating due to an enlarged prostate gland

you are presently taking a prescription **Ask a doctor or pharmacist before use if** drug for high blood pressure.

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 ir redness, irritation, swelling,

pain or other symptoms develop or increase. Some people can develop allergic reactions to ingredients in this product.

, ask a health professional before use. If pregnant or breast-feeding

- 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

. If swallowed, get medical help or contact a **Keep out of reach of children** Poison Control Center right away.

Adults: Directions

-when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gentlydry 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 r in the morningor after each bowel movement.

hildren under 12 years of age: consult a doctor.

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

aloe barbadensis leaf extract, Inactive ingredients

carboxymethylcellulose sodium, cetyl alcohol, glyceryl monostearate,

methylparaben, paraffin, propylene glycol, propylparaben, stearic acid, tween 80, water, xanthan gum



FAMILY WELLNESS						
glycerin, phenylephrine hcl, pramoxine hcl, petrolatum cream						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:69571-004		
Route of Administration	TOPICAL					
	-					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Str	ength	Strength	
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)			GLYCERIN		14.4 g in 100 g	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -					0.25 g	

I	UNII:1W5297W6MV)	r nein i Ler nriine	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: 2300U9XXE4)				
PARAFFIN (UNII: 1900E3H2ZE)				
METHYLPARABEN (UNII: A218C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69571-004- 02	1 in 1 BOX	03/14/2017			
1	NDC:69571-004- 01 26 g in 1 TUBE; Type 0: Not a Combination Product					
Marketing Information						
	Markating	Application Number or Menegraph	Markating Start	Markating End		

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/14/2017	

Labeler - FRONT PHARMACEUTICAL PLC (530897792)

Establishment					
Name	Address	ID/FEI	Business Operations		
FRONT PHARMACEUTICAL PLC		530897792	manufacture(69571-004)		

Revised: 10/2023

FRONT PHARMACEUTICAL PLC