

**FAMILY WELLNESS- mineral oil, petrolatum, phenylephrine hcl ointment
FRONT PHARMACEUTICAL PLC**

Active ingredients (in each gram)

Mineral oil 14%

Petrolatum 74.9%

Phenylephrine HCl 0.25%

Purposes

Protectant

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Vasoconstrictor

- helps relieve the local itching and discomfort associated with hemorrhoids. **Uses**
- Temporarily shrinks hemorrhoid tissue and relieves burning.
- Temporarily provides a coating for relief of anorectal burning.
- Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less

painful

Warnings

For external and/or intrarectal 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.

Stop use and ask a doctor if

- bleeding occurs •condition worsens or does not improve within 7 days.
- introduction of the applicator into the rectum causes additional pain.

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

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

away.

Directions

Adults and children 12 years of age and older for topical use:

- clean the affected area, and pat or dab dry before applying ointment.
- apply to the affected area up to 4 times daily, especially after each bowel movement.

For intrarectal use:

- attach included applicator to tube.
- lubricate applicator tip and gently insert into rectum
- thoroughly clean applicator after each use, and replace cover

Children under 12 years of age: ask a doctor before use.

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

beeswax, benzoic acid, cetyl alcohol, glycerin, laureth-23, **Inactive ingredients** methylparaben, propylparaben, stearyl alcohol

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



FAMILY WELLNESS

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69571-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	74.9 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69571-006-02	1 in 1 BOX	03/30/2017	
1	NDC:69571-006-01	57 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 Drug	M015	03/30/2017	

Labeler - FRONT PHARMACEUTICAL PLC (530897792)

Establishment

Name	Address	ID/FEI	Business Operations
FRONT PHARMACEUTICAL PLC		530897792	manufacture(69571-006)

Revised: 10/2023

FRONT PHARMACEUTICAL PLC