

FAMILY WELLNESS- phenylephrine hcl, petrolatum, mineral ointment
Zhejiang Jingwei Pharmaceutical Co., Ltd.

Drug Facts

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

Active Ingredients (in each gram)

Mineral oil 14 %

Petrolatum 74.9 %

Phenylephrine HCl 0,25 %

Purposes

--- Protectant

---Protectant

---Vasoconstrictor

Uses - Helps relieve the local itching and discomfort associated with hemorrhoids.

-Temporarily shrinks hemorrhoid tissue and relieves burning

-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 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 due to 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

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 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

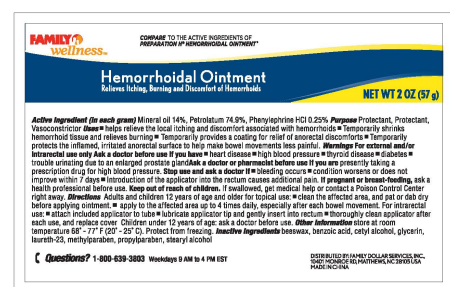
-lubricate applicator tip and gently insert into rectum

-thoroughly clean applicator after each use and replace cover.

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

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

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



FAMILY WELLNESS

phenylephrine hcl, petrolatum, mineral ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55621-006
Route of Administration	TOPICAL, RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
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

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:55621-006-01	1 in 1 BOX	11/01/2013	
1		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	11/01/2013	

Labeler - Zhejiang Jingwei Pharmaceutical Co., Ltd. (530876549)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Jingwei Pharmaceutical Co., Ltd.		530876549	manufacture(55621-006)

Revised: 10/2023

Zhejiang Jingwei Pharmaceutical Co., Ltd.