THERAPLUS PLUS- phenylephrine hci ointment Zhejiang Jingwei Pharmaceutical Co., Ltd.

Drug Facts

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

Active Ingredient (in each gram)

Mineral oil 14%

Petrolatum 74.9%

Phenylephrine HCI 0.25%

Warnings

For external and/or intrarectal use only

Purpose

Protectant

Protectant

Vasoconstrictor

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

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

Directions

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

- -clean the affected area, and oat 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

, ask a health professional before use $\boldsymbol{\mathsf{If}}$ $\boldsymbol{\mathsf{pregnant}}$ or $\boldsymbol{\mathsf{breast-feeding}}$

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 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





THERAPLUS PLUS

phenylephrine hci ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55621-005
Route of Administration	TOPICAL		

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: 85KN0B0MIM)		

CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A218C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:55621-005- 01	42 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/01/2013	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Jingwei Pharmaceutical Co., Ltd.		530876549	manufacture(55621-005)	

Revised: 10/2023 Zhejiang Jingwei Pharmaceutical Co., Ltd.