PREFERRED PLUS HEMORRHOIDAL- phenylephrine hydrochloride, witch hazel cream
Kinray Inc.

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.

Drug Facts

Active ingredients

Phenylephrine hydrochloride 0.25%

Witch hazel 50.0%

Vasoconstrictor

Astringent

Uses

- temporarily relieves irritation and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- 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

When using this product

- do not exceed the recommended daily dosage
- do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- bleeding occur
- condition gets worse or does not Improve within 7 days

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 and gently dry the affected area by patting or blotting with an

appropriate cleansing tissue or soft cloth before applying gel
- when first opening the tube, puncture foil seal with top end of cap
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- **Children under 12 years of age:** ask a doctor

Other information
- store at 20°-25°C (68°-77°F)
- for lot number and expiration date, see crimp of tube or see box

Inactive ingredients
- aloe barbadensis leaf juice, disodium EDTA, hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, tocopheryl acetate (Vitamin E)

Principal Display Panel - 1 oz Carton Label

TAMPER-EVIDENT: Do not use if printed "safety sealed" overwrap is broken or missing.

NDC 61715-093-01

Preferred Plus Pharmacy®

HEMORRHOIDAL

Cooling Gel with aloe

***Compare to the active ingredients in PREPARATION H® Cooling Gel**

Fast Cooling Relief
- Clean, Non-Greasy Formula with No Unpleasant Scent
- Prompt Cooling Relief from Painful Burning and Itching
- Shrinks Swollen Hemorrhoidal Tissue
- Relieves External Discomfort

SATISFACTION GUARANTEED

Preferred Plus Pharmacy®

NET WT 1 OZ (28 g)

PREFERRED PLUS HEMORRHOIDAL

phenylephrine hydrochloride, witch hazel cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61715-093
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
phenylephrine hydrochloride (UNII: 04JA59TNSJ) (phenylephrine - UNII:1WS297W6MV)	phenylephrine hydrochloride	2.5 mg in 1 L
witch hazel (UNII: 101I4J0U34) (witch hazel - UNII:101I4J0U34)	witch hazel	500 mg in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
edetate disodium (UNII: 7FLD91C86K)	
hydroxyethyl cellulose (100 mpa.s at 2%) (UNII: R33S7TK2EP)	
methylparaben (UNII: A2I8C7HI9T)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	

water (UNII: 059QF0KO0R)	
sodium citrate (UNII: 1Q73Q2JULR)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-093-01	1 in 1 CARTON		
1		0.028 L in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/28/2014	

Labeler - Kinray Inc. (012574513)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Products		157469086	MANUFACTURE(61715-093)

Revised: 3/2014 Kinray Inc.