

## **HEMORRHOIDAL COOLING GEL - phenylephrine and witch hazel gel**

**Amerisource Bergen**

*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.*

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### **DRUG FACTS**

#### **ACTIVE INGREDIENT**

Phenylephrine HCl, 0.25%

Witch Hazel, 50%

#### **PURPOSE**

Vasoconstrictor

Astringent

#### **USES**

- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporary relief of itching and burning
- 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
- thyroid disease
- high blood pressure
- diabetes
- difficulty in urination due to enlargement of the prostate

#### **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 unless directed by a doctor
- do not put into the rectum using fingers or any mechanical device or applicator

#### **Stop use and ask a doctor**

- if bleeding occurs
- condition worsens or does not improve within 7 days

**If pregnant or breastfeeding,**

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 the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a 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:** ask a doctor.

### **OTHER INFORMATION**

Store at room temperature: 20° - 25° C (68° - 77° F)

### **INACTIVE INGREDIENTS**

aloe barbadensis gel, benzophenone-4, edetate disodium, hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, sodium citrate, vitamin E, water

### **PACKAGE INFORMATION**

GOOD NEIGHBOR PHARMACY

NDC 24385-421-06

### **HEMORRHOIDAL**

#### **Cooling Gel**

#### **with Vitamin E and Aloe**

Fast cooling relief from painful burning and itching

Net Wt. 0.9 oz. (26 g)

Fast cooling relief

- Clear, non-greasy formula with no unpleasant scent
- Prompt cooling relief from painful burning and itching
- Shrinks swollen hemorrhoidal tissue
- Relieves external discomfort

\*Compare to active ingredients in Preparation H® Cooling Gel

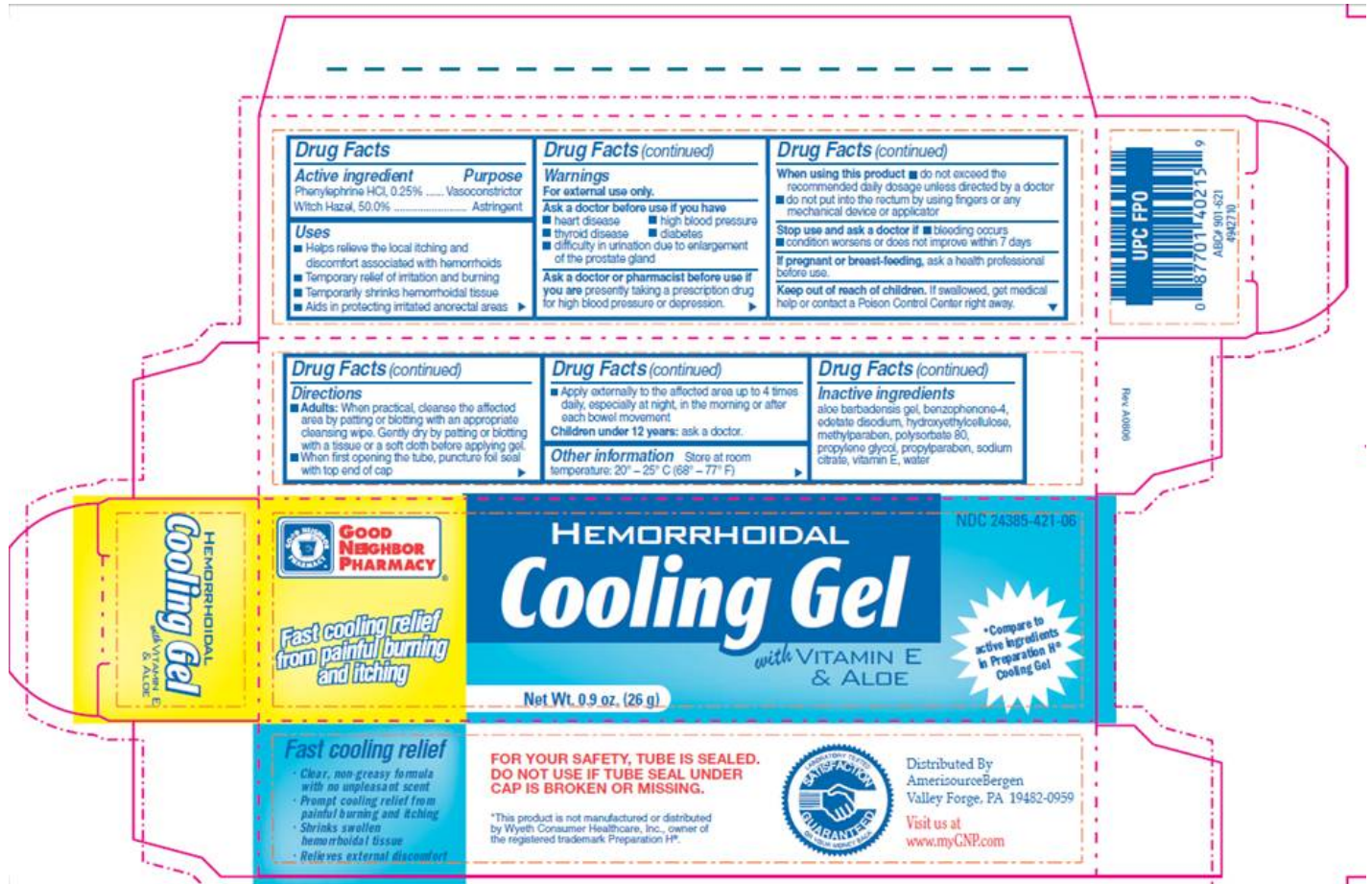
**FOR YOUR SAFETY, TUBE IS SEALED. DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING.**

\*This product is not manufactured or distributed by Wyeth Consumer Healthcare, Inc., owner of the

registered trademark Preparation H®.

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## HEMORRHOIDAL COOLING GEL

phenylephrine and witch hazel gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24385-421
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59 TNSJ) (PHENYLEPHRINE - UNII:1WS29 7W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 1 g
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	50 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24385-421-06	1 in 1 BOX		
1		26 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	08/01/2006	

**Labeler** - Amerisource Bergen (007914906)

Revised: 1/2010

Amerisource Bergen