

## CVS HEMORRHOIDAL COOLING - witch hazel, phenylephrine hydrochloride gel

CVS Pharmacy

*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 ingredients

#### Purpose

Phenylephrine hydrochloride 0.25%.....Vasoconstrictor  
Witch hazel 50.0%.....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

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

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**Other information-** store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F)

### Warnings

**For external 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

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- 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 into rectum by 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

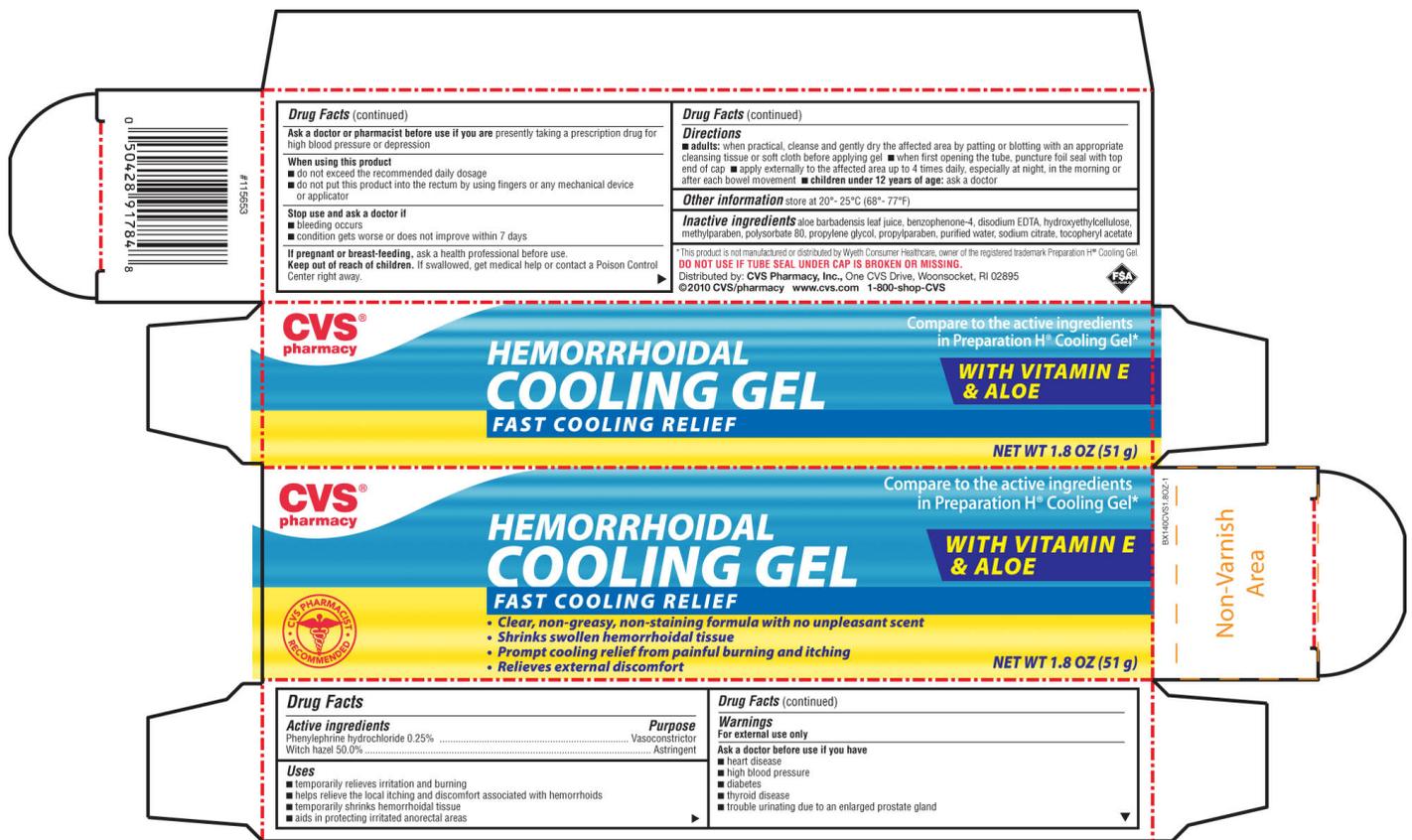
**If pregnant or breast feeding,** ask a health professional before use.

**Keep out of the 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

**Inactive Ingredients** aloe barbadensis leaf juice, benzophenone-4, disodium EDTA, hydroxyethylcellulose, methyl paraben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, tocopheryl acetate



## CVS HEMORRHOIDAL COOLING

witch hazel, phenylephrine hydrochloride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-265
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>WITCH HAZEL</b> (UNII: 10114J0U34) (WITCH HAZEL - UNII:10114J0U34)	WITCH HAZEL	500 mg in 1 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SULISOBENZONE</b> (UNII: 1W6L629B4K)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE (4000 MPAS FOR 1% AQUEOUS SOLUTION) (UNII: ZYD53NBL45)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-265-61	1 in 1 CARTON		
1		51 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/18/2010	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Pharma Pac, LLC (140807475)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture