

**REXALL HEMORRHOIDAL COOLING - witch hazel, phenylephrine hydrochloride gel  
DOLLAR GENERAL**

*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)  
- for lot number and expiration date, see crimp of tube or see box

**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, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, tocopheryl acetate



## REXALL HEMORRHOIDAL COOLING

witch hazel, phenylephrine hydrochloride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:559 10-603
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 1I4J0 U34) (WITCH HAZEL - UNII:10 1I4J0 U34)	WITCH HAZEL	500 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 0 4JA59 TNSJ) (PHENYLEPHRINE - UNII:1WS29 7W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 0 59QF0 KO0R)	
SULISOBENZONE (UNII: 1W6L6 29B4K)	
PROPYLENE GLYCOL (UNII: 6DC9Q 167V3)	
POLYSORBATE 80 (UNII: 6OZP39 ZG8H)	

ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	
METHYL PARABEN (UNII: A2I8C7H9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-603-61	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** - DOLLAR GENERAL (068331990)

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

### Establishment

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

Revised: 11/2010

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