

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

**Walgreen Company**

*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, 50.0%

#### **PURPOSE**

Vasoconstrictor

Astringent

#### **USES**

- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporary relief of irritation 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 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 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 - TUBE**

Walgreens

FOR YOUR SAFETY, TUBE IS SEALED. DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING. This package has an outer carton. Do not buy if outer carton is missing.

### **HEMORRHOIDAL**

#### **Cooling Gel**

*Fast Cooling Relief with Aloe*

- Clear, non-greasy formula with no unpleasant odor
- Relief from painful burning and itching
- Shrinks swollen hemorrhoidal tissue
- With vitamin E

NET WT 0.9 OZ (26 g)

Distributed by Walgreens Co. Deerfield, IL 60015-4616

Made in U.S.A.

*100% Satisfaction Guaranteed*

*www.walgreens.com*

<b>Drug Facts</b> <span style="float: right;">Rev. A</span>		<b>Drug Facts (cont'd)</b>	<b>Drug Facts (cont'd)</b>
<b>Active ingredient</b> Phenylephrine HCl, 0.25% ..... Vasoconstrictor Witch Hazel, 50.0% ..... Astringent	<b>Purpose</b>	<ul style="list-style-type: none"> <li>■ do not exceed the recommended daily dosage unless directed by a doctor</li> <li>■ do not put into the rectum by using fingers or any mechanical device or applicator. <b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>■ bleeding occurs</li> <li>■ condition worsens or does not improve within 7 days.</li> </ul> </li> <li><b>If pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	<b>Children under 12 years:</b> ask a doctor.
<b>Uses</b> <ul style="list-style-type: none"> <li>■ Helps relieve the local itching and discomfort associated with hemorrhoids</li> <li>■ Temporary relief of irritation and burning</li> <li>■ Temporarily shrinks hemorrhoidal tissue</li> <li>■ Aids in protecting irritated anorectal areas</li> </ul>			<b>Other information</b> Store at room temperature: 20° – 25° C (68° – 77° F)
<b>Warnings</b> For external use only. Ask a doctor before use if you have <ul style="list-style-type: none"> <li>■ heart disease</li> <li>■ high blood pressure</li> <li>■ thyroid disease</li> <li>■ diabetes</li> <li>■ difficulty in urination due to enlargement of the prostate gland.</li> </ul> Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression. <b>When using this product</b>	<b>Directions</b> 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. <ul style="list-style-type: none"> <li>■ When first opening the tube, puncture foil seal with top end of cap.</li> <li>■ Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.</li> </ul>		<b>Inactive ingredients</b> aloe barbadensis gel, benzophenone-4, edetate disodium, hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, sodium citrate, vitamin E, water
		<b>FOR YOUR SAFETY, TUBE IS SEALED. DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING. This package has an outer carton. Do not buy if outer carton is missing.</b>	
<b>Hemorrhoidal</b> <i>Cooling Gel</i>		<b>Fast Cooling Relief with Aloe</b> <ul style="list-style-type: none"> <li>• Clear, non-greasy formula with no unpleasant odor</li> <li>• Relief from painful burning and itching</li> <li>• Shrinks swollen hemorrhoidal tissue</li> <li>• With vitamin E</li> </ul>	
		<b>NET WT 0.9 OZ (26 g)</b>	

**PACKAGE INFORMATION - CARTON**

Walgreens

NDC 0363-0400-16

Retain Carton for Complete Information

**HEMORRHOIDAL  
Cooling Gel**

*Fast Cooling Relief with Aloe*

- Clear, non-greasy formula with no unpleasant odor
- Relief from painful burning and itching
- Shrinks swollen hemorrhoidal tissue
- With vitamin E

NET WT 0.9 OZ (26 g)

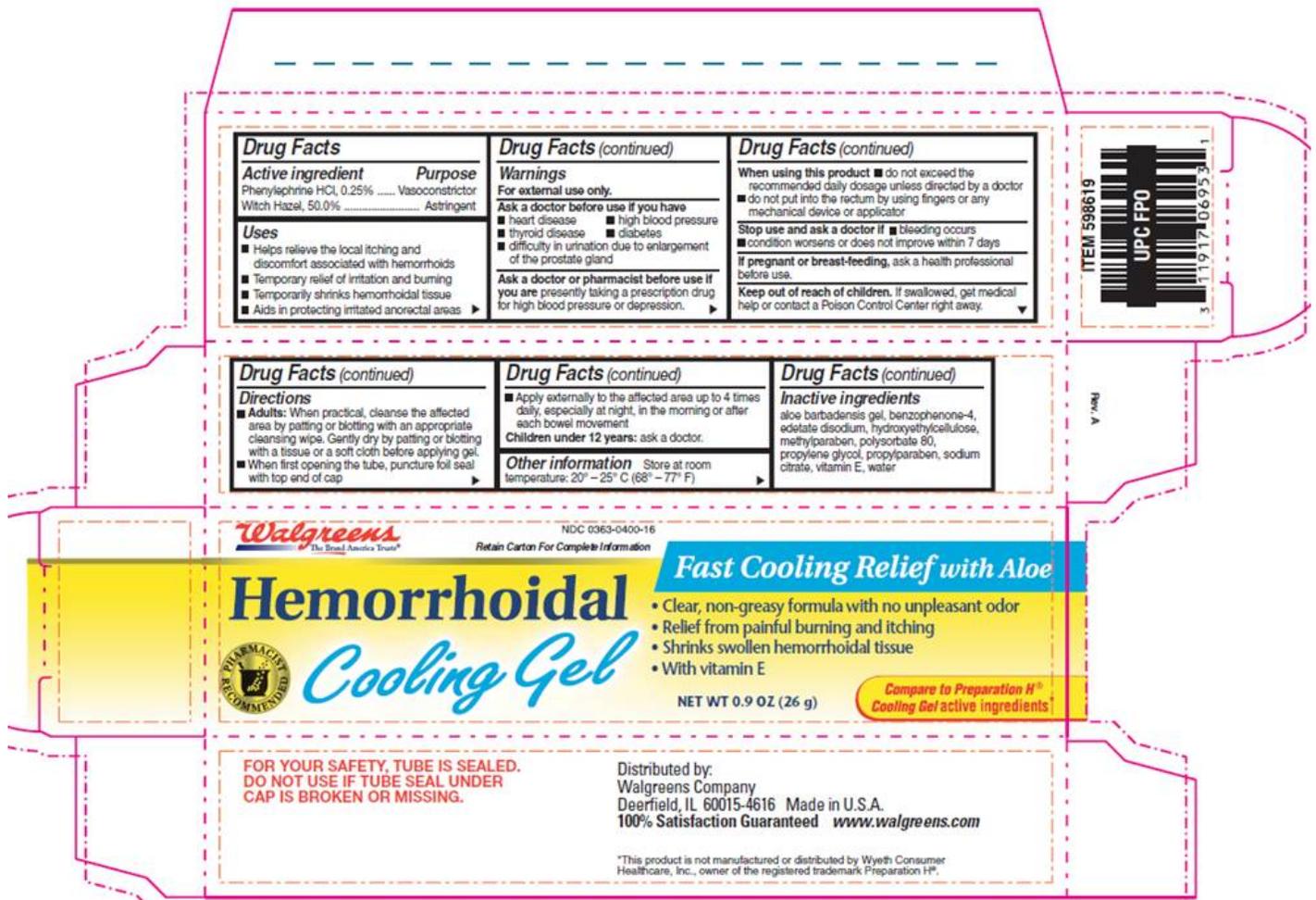
Compare to *Preparation H® Cooling Gel* active ingredients\*

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

Distributed by Walgreens Company  
Deerfield, IL 60015-4616 Made in U.S.A.

100% Satisfaction Guaranteed [www.walgreens.com](http://www.walgreens.com)

\*This product is not manufactured or distributed by Wyeth Consumer Healthcare, Inc., owner of the registered trademark Preparation H®.



## HEMORRHOIDAL COOLING GEL

phenylephrine and witch hazel gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0400
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 1 g
<b>WITCH HAZEL</b> (UNII: 10114J0U34) (WITCH HAZEL - UNII:10114J0U34)	WITCH HAZEL	50 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SULISOBENZONE</b> (UNII: 1W6L629B4K)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0400-16	1 in 1 BOX		
1		26 g in 1 TUBE		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/01/2006	

**Labeler** - Walgreen Company (008965063)

Revised: 2/2010

Walgreen Company