

**HEMORROIDAL COOLING GEL- phenylephrine, witch hazel gel**  
**Trifecta Pharmaceuticals Usa Llc**

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**Hemorrhoidal Cooling Gel**

**Drug Facts**

**Active Ingredient**

Phenylephrine HCl 0.25%

**Purpose**

Vasoconstrictor

**Active Ingredient**

Witch Hazel 50%

**Purpose**

Astringent

**Uses**

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

**Stop use and ask a doctor**

- bleeding occurs
- condition worsens or does not improve within 7 days
- introduction of applicator into the rectum causes additional pain

**If pregnant or breast feeding**

Ask a doctor before use

**Keep out of the reach of children**

If swallowed get medical help or contact Poison Control Center right away

## **Directions**

Children under 12 years of age; ask a doctor before use

Adults: when practical, clean the affected area by patting or blotting with an appropriate cleansing wipe

- gently dry by patting or blotting with a tissue or soft cloth before applying
- when first opening tube, remove foil seal
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement

## **Warnings**

### **For External Use Only**

#### **Ask doctor before use if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty urinating due to an enlarged prostate gland

**Ask doctor 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 by using fingers or any mechanical device or applicator

## **Other information**

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

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®

## **Inactive Ingredients**

Aloe barbadensis gel, benzophenone-4, Acetate disodium, Hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, sodium citrate, Vitamin E, water

## **Questions or Comments**

Call Toll Free 1-888-296-9067

## **Distributed By**

# Trifecta Pharmaceuticals USA™

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301, USA

1-888-296-9067

## Packaging

OUTSIDE BOX

**HEMORRHOIDAL COOLING GEL with Vitamin E and Aloe**

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

0 40232 62271 7

X001GMOLUH

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LOT:  
EXP:

**COMPARE TO** the active ingredients in **PREPARATION H® COOLING GEL**

**HEMORRHOIDAL COOLING GEL**  
with Vitamin E and Aloe

**Net Wt. 1.8 oz. (51g)**

NDC: 69396-032-18

**Fast Cooling Relief**

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

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<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> Phenylephrine HCl 0.25% Witch Hazel 50%</p> <p><b>Purpose</b> Vasoconstrictor Astringent</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ helps relieve the local itching and discomfort associated with hemorrhoids</li> <li>■ temporarily relief of irritation and burning</li> <li>■ temporarily shrinks hemorrhoidal tissue</li> <li>■ aids in protecting irritated anorectal areas</li> </ul> <p><b>Warnings</b></p> <p><b>For external use only</b></p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ heart disease</li> <li>■ high blood pressure</li> <li>■ thyroid disease</li> <li>■ diabetes</li> <li>■ difficulty urinating due to an enlarged prostate gland</li> </ul> <p><b>Ask a doctor before use if you are</b> presently taking a prescription drug for high blood pressure or depression</p> <p><b>When using this product</b></p> <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</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Other Information</b> Store at room temperature 20°-25°C (68°-77°F)</p> <p><b>Inactive Ingredients</b> Aloe barbadensis gel, Acetate disodium, Benzophenone-4, Hydroxyethylcellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Sodium citrate, Vitamin E, Water</p> <p><b>Questions or Comments?</b> Call Toll Free 1-888-296-9067</p> <p>Distributed by: <b>Trifecta Pharmaceuticals USA®</b> 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301 USA Product of PRC <a href="http://www.trifecta-pharma.com">www.trifecta-pharma.com</a></p>
<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ bleeding occurs</li> <li>■ condition worsens or does not improve within 7 days</li> </ul> <p><b>If pregnant or breast-feeding</b>, ask a doctor before use</p> <p><b>Keep out of reach of children.</b> If swallowed get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> Children under 12 years of age: ask a doctor before use Adults: when practical, clean the affected area by patting or blotting with an appropriate cleansing wipe</p> <ul style="list-style-type: none"> <li>■ gently dry by patting or blotting with a tissue or soft cloth before applying</li> <li>■ when first opening tube, remove foil seal</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>	<p><b>Drug Facts (continued)</b></p> <p><b>Other Information</b> Store at room temperature 20°-25°C (68°-77°F)</p> <p><b>Inactive Ingredients</b> Aloe barbadensis gel, Acetate disodium, Benzophenone-4, Hydroxyethylcellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Sodium citrate, Vitamin E, Water</p> <p><b>Questions or Comments?</b> Call Toll Free 1-888-296-9067</p>

INNER TUBE

**COMPARE TO** the active ingredients in **PREPARATION H® COOLING GEL**

**HEMORRHOIDAL COOLING GEL**  
with Vitamin E and Aloe

**Net Wt. 1.8 oz. (51g)**

NDC: 69396-032-18

**Fast Cooling Relief**

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# HEMORRHOIDAL COOLING GEL

phenylephrine, witch hazel gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-032
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>WITCH HAZEL</b> (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	WTCH HAZEL	0.5 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SULISOBENZONE</b> (UNII: 1W6L629B4K)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69396-032-18	1 in 1 BOX	02/13/2018	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M015	02/13/2018	

**Labeler** - Trifecta Pharmaceuticals Usa Llc (079424163)

