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

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# **Hemorrhoidal Cooling Gel**

## **Drug Facts**

## **Active Ingredient**

Phenylephrine HCI 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™

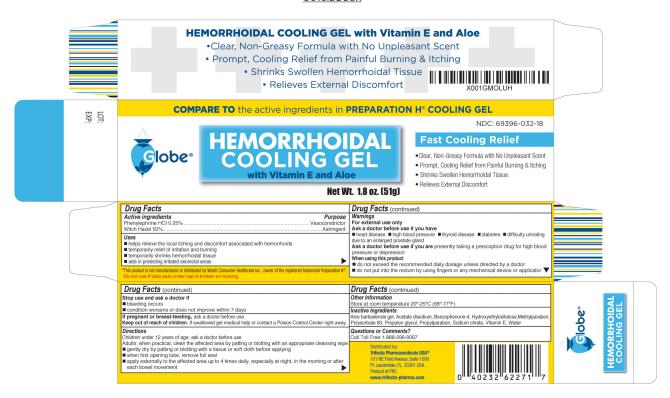
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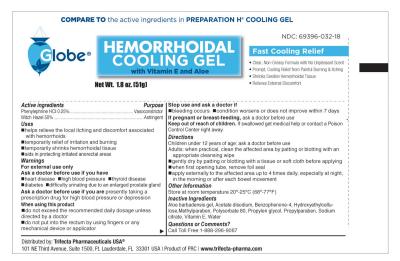
1-888-296-9067

#### **Packaging**

#### **OUTSIDE BOX**



#### <u>INNER TUBE</u>



phenylephrine, witch hazel gel

Product Information				
Product Type	HUMAN OTC DRUG	AN OTC DRUG Item Code (Source)		
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
WITCH HAZEL (UNII: 10114J0U34) (WTCH HAZEL - UNII:10114J0U34)	WTCH HAZEL	0.5 g in 100 g	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g	

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

l	Packaging				
	# Item C	ode Package Descript	ion Marketing Start Date	Marketing End Date	
	NDC:69396	6-032- 1 in 1 BOX	02/13/2018		
	1	56 g in 1 TUBE; Type 0: Not a Co Product	mbination		

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

# Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 12/2024 Trifecta Pharmaceuticals Usa Llc