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

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.

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^{\otimes}

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™

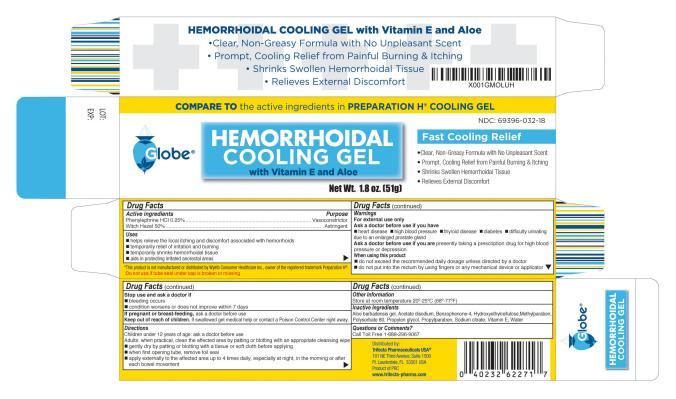
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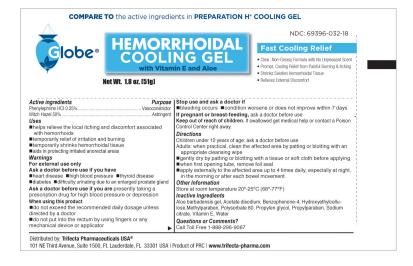
1-888-296-9067

Packaging

OUTSIDE BOX



<u>INNER TUBE</u>



HEMORROIDAL COOLING GEL

phenylephrine, witch hazel gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
WITCH HAZEL (UNII: 10114J0U34) (WTCH HAZEL - UNII:10114J0U34)	WITCH 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: 60ZP39ZG8H)		
METHYLPARABEN (UNII: A218C7H19T)		
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: Z8IX2SC10H)		
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
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				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	02/13/2018		

Revised: 1/2023 Trifecta Pharmaceuticals Usa Llc