

HEMORROIDAL COOLING GEL- phenylephrine, witch hazel gel
Chain Drug Marketing Association

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 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

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)

** This product is not manufactured or distributed by Pfizer Consumer Healthcare, 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 1-800-935-2362

Distributed by

C.D.M.A. Inc. ©

43157 W 9 Mile Rd.

Novi, MI. 48375 USA

1-800-935-2362

www.qualitychoice.com

Product of PRC

Packaging

OUTSIDE BOX

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

NDC 6


QC QUALITY CHOICE

Hemorrhoidal Cooling Gel

Compare to the Active Ingredients in Preparation H® Cooling Gel

Provides Relief of: Painful Burning & Itching | External Discomfort **Enriched With Aloe**

1.8 oz (Net Wt 51 g)

<p>Drug Facts</p> <p>Active ingredients Phenylephrine HCl 0.25% Witch Hazel 50%</p> <p>Purpose Vasconstrictor Astringent</p> <p>Uses ■ helps relieve the local itching and discomfort associated with hemorrhoids ■ temporarily relieves irritation and burning ■ temporarily shrinks hemorrhoidal tissue ■ aids in protecting irritated anorectal areas</p>	<p>Drug Facts (continued)</p> <p>Warnings For external use only Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ due to an enlarged prostate gland Ask a 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</p>
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INSIDE TUBE

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Packaging

OUTSIDE BOX

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

NDC 63868-483

Hemorrhoidal Cooling Gel
OTC Drug Product

Provides Relief of: Painful Burning & Itching | External Discomfort Enriched With Aloe

1.8 oz (Net Wt 51 g)

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INSIDE TUBE

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OTC Drug Product

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HEMORROIDAL COOLING GEL

phenylephrine, witch hazel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-483
Route of Administration	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	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)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-483-18	1 in 1 BOX	07/15/2019	
1		51 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	07/15/2019	

Labeler - Chain Drug Marketing Association (011920774)**Registrant** - Trifecta Pharmaceuticals USA (079424163)

Revised: 7/2019

Chain Drug Marketing Association