

HEMORROIDAL COOLING GEL- phenylephrine, witch hazel gel
Pharmacy Value Alliance, LLC

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)

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

Premier Value Alliance, LLC.

407 East Lancaster Avenue

Wayne, PA. 19087 USA

Product of PRC

Packaging

Hemorrhoidal Cooling Gel

OUTER 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

HEMORRHOIDAL COOLING GEL
with Vitamin E and Aloe

NET WT. 0.9 OZ (26g)

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

<p>Drug Facts</p> <p>Active Ingredients</p> <p>Phenylephrine HCl 0.25% Vasoconstrictor Witch Hazel 50% Astringent</p> <p>Uses</p> <ul style="list-style-type: none">■ 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 <p><small>*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Preparation H®. Do not use if tube seal under cap is broken or missing</small></p>	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>For external use only Ask a doctor before use if you have</p> <ul style="list-style-type: none">■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ diff due to an enlarged prostate gland <p>Ask a doctor before use if you are presently taking a prescription drug pressure or depression</p> <p>When using this product</p> <ul style="list-style-type: none">■ do not exceed the recommended daily dosage unless directed by a d■ do not put into the rectum by using fingers or any mechanical device
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INNERTUBE

HEMORRHOIDAL COOLING GEL
with Vitamin E and Aloe

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HEMORROIDAL COOLING GEL

phenylephrine, witch hazel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	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)	
.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:68016-054-09	1 in 1 BOX	08/02/2018	
1		26 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 Drug	M015	08/02/2018	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Revised: 12/2024

Pharmacy Value Alliance, LLC