

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

LOT:
EXP:



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 ■ difficulty due to an enlarged prostate gland <p>Ask a doctor before use if you are presently taking a prescription drug for high blood 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 doctor ■ do not put into the rectum by using fingers or any mechanical device or applicator
<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ bleeding occurs ■ condition worsens or does not improve within 7 days <p>If pregnant or breast-feeding, ask a doctor before use</p> <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>Children under 12 years of age: ask a doctor before use</p> <p>Adults: when practical, clean the affected area by patting or blotting with an appropriate cleansing wipe</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <p>Other Information</p> <p>Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive Ingredients</p> <p>Aloe vera leaf extract, Edetate disodium, Hydroxyethyl cellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Purified water, Sodium citrate, Sulfisobenzonazole, Vitamin E acetate</p> <p>Questions or Comments?</p> <p>Call Toll Free 1-888-296-9067</p> <p><small>Distributed By: Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19087 Product of PRC</small></p> <div style="text-align: right;">  <p><small>If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.</small></p> </div>

INNERTUBE

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

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HEMORRHOIDAL 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:1W5297W6MV)	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: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZ N16)	

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 final	part346	08/02/2018	

Labeler - Pharmacy Value Alliance, LLC (101668460)**Registrant** - Trifecta Pharmaceuticals USA LLC (079424163)