

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

LOT:
EXP:





Hemorrhoidal Cooling Gel

External Use Only - Prescription Free Formula


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

1.8 oz (Net Wt 51 g)

*Compare to the Active Ingredients in Preparation H® Cooling Gel

<p>Drug Facts</p> <p>Active ingredients Phenylephrine HCl 0.25% Vasconstrictor Witch Hazel 50% Astringent</p> <p>Purpose Vasconstrictor Astringent</p> <p>Uses <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <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>
<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if <ul style="list-style-type: none"> ■ bleeding occurs ■ condition worsens or does not improve within 7 days If pregnant or breast-feeding, ask a doctor before use Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>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 <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>	<p>Drug Facts (continued)</p> <p>Other information Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive ingredients Aloe barbadensis leaf extract, Edetate disodium, Hydroxyethyl cellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Purified water, Sodium Citrate, Sulfobenzonate, Vitamin E acetate</p> <p><small>* This product is not manufactured or distributed by Pfizer Consumer Care, the registered trademark owner of Preparation H®</small></p> <div style="display: flex; align-items: center;">  <p style="font-size: 8px;">Distributed by C.D.M.A., Inc.® 4315 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2582</p> </div> <p style="text-align: center;">Product of PRC</p> <div style="text-align: right;">  <p>6 35515 1</p> </div>

INSIDE TUBE




*Compare to the Active Ingredients in Preparation H® Cooling Gel

Hemorrhoidal Cooling Gel

External Use Only - Prescription Free Formula

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

1.8 oz (Net Wt 51 g)

<p>Active ingredients Phenylephrine HCl 0.25% Vasconstrictor Witch Hazel 50% Astringent</p> <p>Purpose Vasconstrictor Astringent</p> <p>Uses <ul style="list-style-type: none"> ■ 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>Warnings For external use only Ask a doctor before use if you have <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty urinating 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 <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>	<p>Stop use and ask a doctor if <ul style="list-style-type: none"> ■ bleeding occurs ■ condition worsens or does not improve within 7 days If pregnant or breast-feeding, ask a doctor before use Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>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 <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> <p>Other information Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive ingredients Aloe barbadensis leaf extract, Edetate disodium, Hydroxyethyl cellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Purified water, Sodium Citrate, Sulfobenzonate, Vitamin E acetate</p> <div style="display: flex; align-items: center;">  <p style="font-size: 8px;">Distributed by C.D.M.A., Inc.® 4315 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2582</p> </div> <p style="text-align: center;">Product of PRC</p>
--	---

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
Enriched With Aloe

Provides Relief of: Painful Burning & Itching | External Discomfort

1.8 oz (Net Wt 51 g)

<p>Drug Facts</p> <p>Active ingredients Phenylephrine HCl 0.25% Witch Hazel 50%</p> <p>Purpose Vasoconstrictor Astringent</p> <p>Uses <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <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 </p>
<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if <ul style="list-style-type: none"> ■ bleeding occurs ■ condition worsens or does not improve within 7 days If pregnant or breast-feeding, ask a doctor before use. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>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 <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>	<p>Drug Facts (continued)</p> <p>Other information Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive ingredients Aloe barbadensis leaf extract, Edetate disodium, Hydroxyethyl cellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Purified water, Sodium Citrate, Vitamin E acetate</p> <p>* This product is not manufactured or distributed by Pfizer Consumer Care, Inc. (owner of the registered trademark Preparation H®)</p> <p style="text-align: right;">Distributed by C.D.M.A., Inc.® 4315 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2582</p> <p style="text-align: center;">Product of PRC</p>

INSIDE TUBE

Hemorrhoidal Cooling Gel
Enriched With Aloe

Provides Relief of: Painful Burning & Itching | External Discomfort

1.8 oz (Net Wt 51 g)

<p>Active ingredients Phenylephrine HCl 0.25% Witch Hazel 50%</p> <p>Purpose Vasoconstrictor Astringent</p> <p>Uses <ul style="list-style-type: none"> ■ 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>Warnings For external use only Ask a doctor before use if you have <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty urinating 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 <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>	<p>Stop use and ask a doctor if <ul style="list-style-type: none"> ■ bleeding occurs ■ condition worsens or does not improve within 7 days If pregnant or breast-feeding, ask a doctor before use. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>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 <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> <p>Other information Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive ingredients Aloe barbadensis leaf extract, Edetate disodium, Hydroxyethyl cellulose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Purified water, Sodium Citrate, Sulfobenzonazo, Vitamin E acetate</p> <p style="text-align: right;">Distributed by C.D.M.A., Inc.® 4315 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2582</p> <p style="text-align: center;">Product of PRC</p>
--	--

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: 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: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)