

CVS HEALTH HEMORRHOIDAL COOLING HEMORRHOIDAL- phenylephrine hydrochloride and witch hazel gel
CVS

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.

CVS HEALTH™ HEMORRHOIDAL COOLING GEL
HEMORRHOIDAL GEL

Drug Facts

Active ingredients	Purpose
Hamamelis virginiana (witch hazel) 50%	Astringent
Phenylephrine hydrochloride 0.25%	Vasoconstrictor

Uses

- temporarily relieves anorectal itching and discomfort associated with hemorrhoids or anorectal disorders
- temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas
- temporary relief of burning

Warnings

For external use only.

Do not use this product

- if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

Ask a doctor or pharmacist before use if you are

- presently taking a prescription drug for high blood pressure or depression

When using this product

- do not exceed recommended daily dosage unless directed by a doctor
- do not put into rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- bleeding occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison

Control Center right away: 800-222-1222.

Directions

Adults

- when practical, cleanse affected area by patting or blotting with appropriate cleansing wipe. Gently dry by patting or blotting with tissue or soft cloth before applying gel
- apply externally to affected area up to 4 times daily or after each bowel movement

Children under 12 years old: Ask a doctor.

Other information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, benzophenone-4, disodium EDTA, hydroxyethylcellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

Questions or comments?

866-323-0107

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 26 g Tube Carton

CVS
Health®

Compare to the active
ingredients in Preparation H®
Cooling Gel*

NDC 69842-843-01

Hemorrhoidal
Cooling Gel

FAST COOLING RELIEF

- Clear, non-greasy formula with soothing aloe & a pleasant scent
- Shrinks swollen hemorrhoidal tissue
- Prompt cooling relief from painful burning & itching

- Relieves external discomfort

Package Contains

One Tube

NET WT 0.9 OZ (26 g)

DO NOT USE IF SEAL ON TUBE
IS PUNCTURED OR MISSING

PL31108B
V04

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*This product is not manufactured or distributed by Wyeth Consumer Healthcare, the distributor of Preparation H®.

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, RI 02895
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CVS.com®
1-800-SHOP CVS

Made in the U.S.A.
V-32922

CVS Quality
Money Back Guarantee

#317686



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phenylephrine hydrochloride and witch hazel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-843
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
WITCH HAZEL (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)	WTCH HAZEL	500 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KOOR)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-843-01	1 in 1 CARTON	11/15/2006	
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	01/01/2004	

Labeler - CVS (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(69842-843)