

HEMORRHOIDAL COOLING- phenylephrine hcl, witch hazel gel

Western Family Foods Inc

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.

Western Family Hemorrhoidal Cooling Gel Drug Facts

Active ingredient

Phenylephrine HCl 0.25%

Witch hazel 50.0%

Purpose

Vasoconstrictor

Astringent

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

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

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 the recommended daily dosage
- do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- bleeding occurs
- condition gets worse or does not improve within 7 days

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.

Directions

- adults: when practical, cleanse and gently dry the affected area by patting or blotting with an appropriate cleansing tissue or soft cloth before applying gel
- when first opening the tube, puncture foil seal with top end of cap
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- children under 12 years of age: ask a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe vera gel, benzophenone-4, edetate disodium, hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, vitamin E

Package/Label Principal Display Panel

HEMMORRHOIDAL Cooling Gel

Fast Cooling Relief

Clear, Non-Greasy Formula with No Unpleasant Scent

Prompt Cooling Relief from Painful Burning And Itching

Shrinks Swollen Hemorrhoidal Tissues

Relieves External Discomfort

WITH VITMAIN E AND ALOE

COMPARE TO THE ACTIVE INGREDIENTS OF PREPARATION H® COOLING GEL



HEMORRHOIDAL COOLING

phenylephrine hcl, witch hazel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-843
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	50.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
EDETATE DISODIUM (UNII: 7FLD9 1C86 K)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8 H)	
PROPYLENE GLYCOL (UNII: 6DC9Q 167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00 R)	

SODIUM CITRATE (UNII: 1Q73Q2JULR)

.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)

SULISOBENZONE (UNII: 1W6L629B4K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-843-24	1 in 1 CARTON		
1		51 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	09/24/2012	

Labeler - Western Family Foods Inc (192166072)

Revised: 10/2012

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