

HEMORRHOIDAL COOLING GEL - phenylephrine and witch hazel gel
McKesson

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.

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
- Temporary relief of 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
- thyroid disease
- high blood pressure
- diabetes
- difficulty in urination due to enlargement of the 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 unless directed by a doctor
- do not put into the rectum using fingers or any mechanical device or applicator

Stop use and ask a doctor

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

If pregnant or breastfeeding,

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 the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a 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: ask a doctor.

OTHER INFORMATION

Store at room temperature: 20° - 25° C (68° - 77° F)

INACTIVE INGREDIENTS

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

PACKAGE INFORMATION - TUBE

Sunmark®

COMPARE TO PREPARATION H® ACTIVE INGREDIENTS*

NDC 49348-811-32

Hemorrhoidal Cooling Gel

Fast Cooling Relief

WITH VITAMIN E AND ALOE

NET WT. 1.8 OZ (51 g)

This tube is sealed and packaged in a carton. Do not buy if carton is missing. Do not use if the seal under the cap has been punctured or if the tube is damaged.

Distributed by McKesson
One Post Street
San Francisco, CA 94104
Money Back Guarantee

Drug Facts	Drug Facts (cont'd)	Drug Facts (cont'd)	Drug Facts (cont'd)
Active ingredient Phenylephrine HCl, 0.25% Vasoconstrictor Witch Hazel, 50.0% Astringent	■ difficulty in urination due to enlargement of the prostate gland.	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Other information Store at room temperature: 20° – 25° C (68° – 77° F)
Uses ■ Helps relieve the local itching and discomfort associated with hemorrhoids ■ Temporary relief of irritation and burning ■ Temporarily shrinks hemorrhoidal tissue ■ Aids in protecting irritated anorectal areas	Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.	Directions Adults: When practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a 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: ask a doctor.	Inactive ingredients aloe barbadensis gel, benzophenone-4, edetate disodium, hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, sodium citrate, vitamin E, water
Warnings For external use only. Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes	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. Stop use and ask a doctor if ■ bleeding occurs ■ condition worsens or does not improve within 7 days. If pregnant or breast-feeding, ask a health professional before use.		Distributed By McKesson One Post Street San Francisco, CA 94104 Money Back Guarantee

Rev. A1106

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COMPARE TO PREPARATION H®
ACTIVE INGREDIENTS*
NDC 49348-811-32

hemorrhoidal cooling gel

Fast Cooling Relief

WITH VITAMIN E & ALOE

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PACKAGE INFORMATION - CARTON

Sunmark®

COMPARE TO PREPARATION H® ACTIVE INGREDIENTS*

NDC 49348-811-32

Hemorrhoidal Cooling Gel

Fast Cooling Relief

Clear, non-greasy formula with no unpleasant scent
Prompt cooling relief from painful burning and itching

WITH VITAMIN E AND ALOE

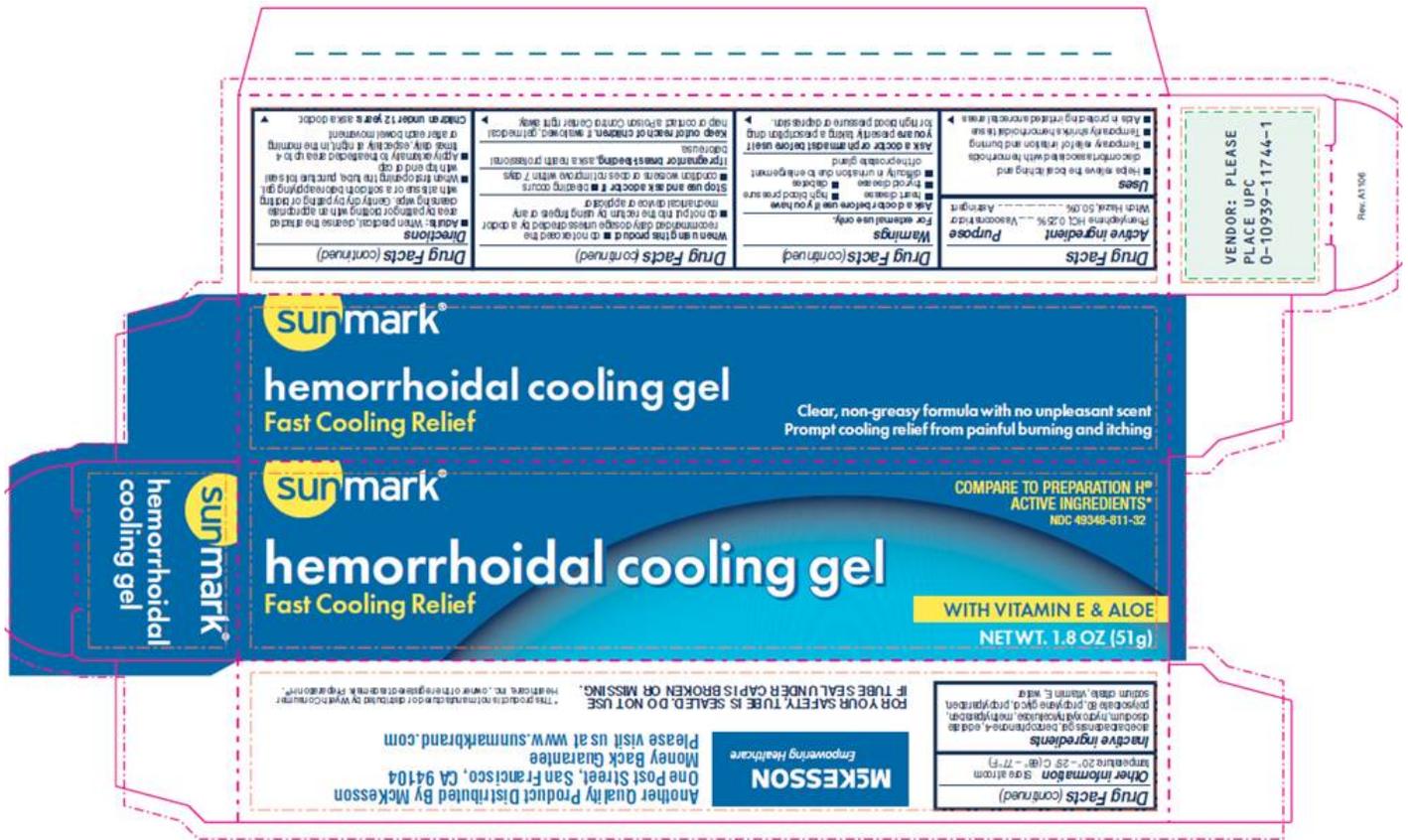
NET WT. 1.8 OZ (51 g)

Another Quality Product Distributed by McKesson
One Post Street, San Francisco, CA 94104
Money Back Guarantee
Please visit us at www.sunmarkbrand.com

FOR YOUR SAFETY, TUBE IS SEALED. DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING.

*This product is not manufactured by Wyeth Consumer Healthcare, Inc., owner of the registered

trademark Preparation H®.



HEMORRHOIDAL COOLING GEL

phenylephrine and witch hazel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-811
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 1 g
WITCH HAZEL (UNII: 10114J0U34) (WITCH HAZEL - UNII:10114J0U34)	WITCH HAZEL	50 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
METHYL PARABEN (UNII: A218C7H9T)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-811-32	1 in 1 BOX		
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	11/15/2006	

Labeler - McKesson (177667227)

Revised: 2/2010

McKesson