

TOPCARE HEMORRHOIDAL- glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream
Topco Associates LLC

Topco Associates LLC. Hemorrhoidal Cream Drug Facts

Active ingredients

Glycerin 14.4%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

White petrolatum 15%

Purpose

Protectant

Vasoconstrictor

Local anesthetic

Uses

- for temporary relief of pain, soreness and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 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
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

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 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 cream.
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover
- children under 12 years of age: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe barbadensis leaf extract, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl monostearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, vitamin E, xanthan gum

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare® health

COMPARE TO PREPARATION H® CREAM ACTIVE INGREDIENTS

MAXIMUM STRENGTH PAIN RELIEF

Hemorrhoidal Cream

SMOOTH CREAM FORMULA WITH ALOE

- Rapid Soothing Pain Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves External Discomfort

WITH ALOE

NET WT 1.8 OZ (51 g)

NO COPY
CODE
AREA

NDC 36800-944-24



COMPARE TO
PREPARATION H® CREAM
ACTIVE INGREDIENTS*

MAXIMUM STRENGTH
PAIN RELIEF

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WITH ALOE

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This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING

COMPARE TO PREPARATION H® CREAM
ACTIVE INGREDIENTS*



WITH ALOE

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Hemorrhoidal Cream SMOOTH CREAM FORMULA WITH ALOE

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DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
TOPCO PERA0122
QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

Drug Facts	Purpose
<p>Active ingredients</p> <p>Glycerin 14.4%.....Proctantol</p> <p>Phenylephrine HCl 0.25%.....Vasoconstrictor</p> <p>Primerone HCl 1%.....Local anesthetic</p> <p>White petrolatum 15%.....Protectant</p>	<p>Temporarily provides a soothing relief of associated discomforts</p> <p>Temporarily protects the irritated, itched anal rectal surface to help make bowel movements less painful</p>
Uses	Warnings
<ul style="list-style-type: none"> • for temporary relief of pain, soreness and burning • helps relieve the local itching and discomfort associated with hemorrhoids • temporarily soothes hemorrhoidal tissue 	<p>For external use only</p> <ul style="list-style-type: none"> • Ask a doctor before use if you have heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland
Directions	Drug Facts (continued)
<p>Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement</p> <p>For application in the lower anal canal, remove cover from dispensing cap. Attach dispensing cap to tube. Loosen dispensing cap well, then gently insert dispensing cap pathway into the anus.</p> <p>Thoroughly cleanse dispensing cap after each use and replace cover</p> <p>Children under 12 years of age: ask a doctor</p>	<p>Temporarily provides a soothing relief of associated discomforts</p> <p>Temporarily protects the irritated, itched anal rectal surface to help make bowel movements less painful</p>
Drug Facts (continued)	Drug Facts (continued)
<p>Directions</p> <ul style="list-style-type: none"> • 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 soft cloth before applying cream. • children: after opening the tube, puncture foil seal with tip of end of cap • apply externally or in the lower portion of the anal canal only 	<p>Temporarily provides a soothing relief of associated discomforts</p> <p>Temporarily protects the irritated, itched anal rectal surface to help make bowel movements less painful</p>

NDC 36800-944-24



Drug Facts (continued)

- condition worsens or does not improve within 7 days
- the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

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: (1-800-222-1222)

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TOPCARE HEMORRHOIDAL

glycerin, phenylephrine hcl, pramoxine hcl, white petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-944
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WW9CM0067Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-944-24	1 in 1 CARTON	11/03/2011	
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 Drug	M015	11/03/2011	

Labeler - Topco Associates LLC (006935977)

Revised: 10/2024

Topco Associates LLC