

HEMORRHOIDAL CREAM- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, white petrolatum cream
Redpharm Drug 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.

Hemorrhoidal Cream

Active ingredients

Glycerin 14.4%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

White petrolatum 15%

Purpose

Protectant

Vasoconstrictor

Local anesthetic

Protectant

Uses

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

Warnings

For external use only.

When using this product

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

Ask a doctor before use if you have

- heart disease

- high blood pressure
- thyroid disease
- diabetes
- difficulty 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.

Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days
- the symptoms being treated do not subside or if redness, irritation, swelling, pain or other symptoms develop or increase. Some people can develop allergic reactions to ingredients in this product.

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 (1-800-222-1222) right away.

Directions

Adults:

- when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- apply externally to the affected area up to 4 times daily, especially at night or in the morning or after each bowel movement.
- apply externally or in the lower portion of the anal canal only.
- 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.

Children under 12 years of age: consult a doctor.

Other Information

store at room temperature 68° - 77° F (20° - 25° C).

Inactive ingredients

aloe barbadensis leaf extract, carboxymethylcellulose sodium, cetyl alcohol, glyceryl monostearate, methylparaben, paraffin, propylene glycol, propylparaben, stearic acid, tween 80, water, xanthan gum

Questions?

1-800-639-3803 Weekdays 9 AM to 4 PM EST

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the symptoms being treated do not subside or if redness, irritation,

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

Stop use and ask a doctor if

prescription drug for high blood pressure or depression.

Ask a doctor or pharmacist before use if you are presently taking a

heart disease ■ high blood pressure ■ thyroid disease ■ diabetes

difficulty urinating due to an enlarged prostate gland

Drug Facts (continued)

■ temporarily provides a cooling for relief of anorectal discomforts

the local itching and discomfort associated with hemorrhoids ■ helps relieve

■ for temporary relief of pain, soreness and burning ■ helps relieve

White petrolatum 15% ■ temporarily provides a cooling for relief of anorectal discomforts

Promoxine HCl 1% ■ temporarily provides a cooling for relief of anorectal discomforts

Phenylephrine HCl 0.25% ■ temporarily provides a cooling for relief of anorectal discomforts

Glycerin 14.4% ■ temporarily provides a cooling for relief of anorectal discomforts

Local anesthetic ■ temporarily provides a cooling for relief of anorectal discomforts

Vasocostrictor ■ temporarily provides a cooling for relief of anorectal discomforts

Protectant ■ temporarily provides a cooling for relief of anorectal discomforts

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Drug Facts (continued)

■ temporarily protects the inflamed irritated anorectal surface to help make bowel movements less painful ■ temporarily shrinks hemorrhoidal tissue

Warnings

When using this product ■ do not put this product into the rectum by using fingers or any mechanical device or applicator ■ do not exceed recommended daily dosage unless directed by a doctor

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Drug Facts

Active ingredients

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Purpose

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NDC 70000-0425-1

Maximum Strength

Hemorrhoidal Cream

Smooth Cream Formula with Aloe

- Rapid, Soothing Pain Relief From Painful Burning, Itching & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue



COMPARE TO PREPARATION H® HEMORRHOIDAL CREAM
active ingredients*

100% Money Back Guarantee

NET WT 1 OZ (28 g)

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HEMORRHOIDAL CREAM			
glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, white petrolatum cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1503(NDC:70000-0425)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	0.28 g in 28 g	
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	4.032 g in 28 g	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.07 g in 28 g	

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)

PETROLATUM

4.2 g
in 28 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0K00R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1503-2	28 g in 1 TUBE; Type 0: Not a Combination Product	04/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/03/2019	

Labeler - Redpharm Drug Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
Redpharm Drug Inc.		828374897	repack(67296-1503)

Revised: 2/2023

Redpharm Drug Inc.