

HEMORRHOIDAL CREAM- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, white petrolatum cream

Cardinal Health, 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

Drug Facts (continued)

■ 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.

Drug Facts (continued)

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

Other Information Store at room temperature 68° - 77° F (20° - 25° C). Children under 12 years of age: consult a doctor.

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 to the affected area up to 4 times daily, especially at night or in the morning or after each bowel movement. ■ apply externally or to the lower portion of the anal canal only. ■ For application in the anal canal: remove cover from dispensing cap. Match dispensing cap to the anus. Lubricate dispensing cap and gently insert dispensing cap partway into the anus. ■ 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 to the affected area up to 4 times daily, especially at night or in the morning or after each bowel movement. ■ apply externally or to the lower portion of the anal canal only. ■ For application in the anal canal: remove cover from dispensing cap. Match dispensing cap to the anus. Lubricate dispensing cap and gently insert dispensing cap partway into the anus.

Inactive ingredients aloe barbadensis leaf extract, carbonylmethylcellulose, propylparaben, stearic acid, triacetin, water, xanthan gum

Drug Facts (continued)

Active ingredients

Glycerin 14.4%
 Pramoxine HCl 0.25%
 Phenylephrine HCl 1%
 White petrolatum 15%
 Local anesthetic
 Vasoconstrictor
 Protectant

Purpose

■ temporarily protects the inflamed/irritated anorectal surface to help make bowel movements less painful ■ temporarily soothes 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

■ 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

Drug Facts (continued)

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



LEADER?

COMPARE TO PREPARATION H® HEMORRHOIDAL CREAM active ingredients*

100% Money Back Guarantee

NET WT 1 OZ (28 g)

*This product is not manufactured or distributed by Pfizer, owner of the registered trademark Preparation H®.

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CIN 5463500 REV. 11/18



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Return to place of purchase if not satisfied.



LEADER? Maximum Strength Hemorrhoidal Cream Smooth Cream Formula with Aloe

HEMORRHOIDAL CREAM

glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, white petrolatum cream

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | 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: 059QF0KO0R) | |
| 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:70000-0425-1 | 1 in 1 BOX | 04/03/2019 | |
| 1 | | 28 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 | 04/03/2019 | |

Labeler - Cardinal Health, Inc. (097537435)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|-------------------------|
| zhejiang jingwei pharmaceutical co., ltd | | 530876549 | manufacture(70000-0425) |

Revised: 9/2020

Cardinal Health, Inc.