

HEMORRHOIDAL CREAM- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, white petrolatum cream
Cardinal Health 110, LLC. dba Leader

MAX STRENGTH PAIN RELIEF 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:

Children under 12 years of age: consult a doctor.

- 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.

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

Package type 70000-0425-1

NDC 70000-0425-1

Maximum Strength

Hemorrhoidal Cream

Smooth Cream Formula with Aloe

LEADERTM

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

NET WT 1 OZ (28 g)

Drug Facts **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 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. 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

©2020 Cardinal Health. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health.

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Made in China

CIN 5463500
REV. 4/20



V-34636



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	12/30/2020	
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 Drug	M015	12/30/2020	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)