

HEMORRHOIDAL CREAM WITH ALOE- glycerol, phenylephrine, pramoxine, petrolatum cream

Chain Drug Marketing Association

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 With Aloe

Drug Facts

Active Ingredient

Glycerol 14.4%

Purpose

Protectant

Active Ingredient

Phenylephrine HCl 0.25%

Purpose

Vasoconstrictor

Active Ingredient

Pramoxine HCl 1%

Purpose

Local Anesthetic

Active Ingredient

Petrolatum 15%

Purpose

Protectant

Uses

Helps relieve the local itching and discomfort associated with hemorrhoids

Temporarily shrinks hemorrhoidal tissue and relieves burning

Temporarily provides a coating for relief of anorectal discomforts

Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Stop use and ask a doctor

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 doctor 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, clean 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.

When first opening 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

Warnings**For External Use Only****Ask doctor before use if you have**

Heart Disease

Thyroid Disease

Diabetes

Difficulty urinating due to an enlarged prostate gland

Ask doctor before use if you are presently taking a prescription 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

Other Information

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

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

Inactive Ingredients

Aloe barbadensis leaf juice, carboxmethylcellulose sodium, cetyl alcohol, glyceryl monostearate, methylparaben, mineral oil, polysorbate 80, propylene glycol, propylparaben, purified water, stearic acid, xanthan gum

Questions or Comments

Call 1-800-935-2362

Distributed By

C.D.M.A., Inc.®

43157 W 9 Mile Rd.

Novi, MI.48375, USA

1-00-935-2362

www.qualitychoice.com

Product of PRC

Packaging

OUTER BOX

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

NDC 63868-561-09

Hemorrhoidal Cream With Aloe
Maximum Strength Pain Relief

Rapid, Soothing Pain Relief from: Painful Burning, Itching & Discomfort

0.9 oz (Net Wt 25.5 g)

Drug Facts

Active ingredients

Glycerol 14.4%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local anesthetic
Petrolatum 15%	Protectant

Purpose

Protectant

Uses

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

Drug Facts (continued)

Warnings

For external use only

Ask a doctor before use if you have

- heart disease ■ thyroid disease ■ diabetes ■ difficulty urinating due to an enlarged prostate gland

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Drug Facts (continued)

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 doctor 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, clean the affected area by patting or blotting with an appropriate cleansing wipe

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Drug Facts (continued)

Other Information

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


Inactive Ingredients

Aloe barbadensis leaf juice, Carboxymethylcellulose sodium, Cetyl alcohol, Glycerol, Monostearate, Methylparaben, Mineral oil, Polysorbate 80, Propylparaben, Propylparaben, Purified water, Stearic acid, Xanthan gum

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INNERTUBE

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Maximum Strength Pain Relief

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Product of PRC

Hemorrhoidal Cream with Aloe

HEMORRHOIDAL CREAM WITH ALOE

glycerol, phenylephrine, pramoxine, petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-561
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 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
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 100-200 MPAS AT 1%) (UNII: 99H65D77XY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-561-09	1 in 1 BOX	07/08/2019	
1		25.5 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	07/07/2019	

Labeler - Chain Drug Marketing Association (011920774)**Registrant** - Trifecta Pharmaceuticals USA (079424163)