

**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.*

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**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](http://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

**Ask a doctor 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
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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

- 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

**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, Propylent glycol, Propylparaben, Purified water, Stearic acid, Xanthan gum

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INNERTUBE

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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, Propylparaben, Mineral oil, Polysorbate 80, Propylent glycol, Purified water, Stearic acid, Xanthan gum

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Hemorrhoidal Cream with Aloe

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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-561
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g
<b>GLYCERIN</b> (UNII: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X)	GLYCERIN	14.4 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 100-200 MPA.S AT 1%)</b> (UNII: 99H65D77XY)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC10H)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ALOE VERA LEAF</b> (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)