

**HEMORRHOIDAL CREAM- glycerol, phenylephrine, pramoxine,  
petrolatum cream  
Trifecta Pharmaceuticals Usa Llc**

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**Hemorrhoidal Cream Maximum Strength Pain Relief**

**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**

White Petrolatum 15%

**Purpose**

Protectant

**Uses**

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

Temporary relief of pain, soreness and burning

### **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 cleaning wipe. Gently dry by patting or blotting with a tissue or soft cloth before applying cream.

When first opening tube remove the foil seal

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

For application in the lower anal canal, remove cover from applicator. Attach applicator to tube. Lubricate applicator well then gently insert applicator pathway into the anus.

Thoroughly cleanse applicator after each use and replace cover.

Children under 12 years of age, ask a doctor.

### **Warnings**

**For External Use Only**

**Ask doctor before use if you have**

Heart Disease

Thyroid Disease

Diabetes

thyroid disease

Difficulty urinating due to enlargement of 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)

### **Inactive Ingredients**

Aloe barbadensis leaf juice, carboxmethylcellulose sodium, cetearyl alcohol, mono and di glycerides, methylparaben, light mineral oil, polysorbate 80, propylene glycol, propylparaben, purified water, stearic acid, xanthan gum

### **Questions or Comments**

Call 1-888-296-9067

### **Distributed By**

**Trifecta Pharmaceuticals USA™**

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301, USA

1-888-296-9067

[www.trifecta-pharma.com](http://www.trifecta-pharma.com)

SKU: 430903-FBA

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

Do not use if tube seal under cap is broken or missing.

# OUTSIDE BOX



# INNER TUBE





# OUTSIDE BOX

EXP. LOT

**HEMORRHOIDAL CREAM with Aloe**

- Rapid, soothing pain relief from painful burning, itching, and discomfort
- Shrinks Swollen Hemorrhoidal Tissue
  - Protects irritated tissue
- Relieves External Discomfort



**\*Compare to the active ingredients in Preparation H® Hemorrhoidal Cream**

NDC: 69396-171-18



**HEMORRHOIDAL CREAM**

**MAXIMUM STRENGTH PAIN RELIEF**

NET WT. 1.8 OZ. (51G)



**Smooth Cream with Aloe**

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

<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b></p> <p>Cyanin 14.4%.....Protectant</p> <p>Phenylephrine HCl 0.25%.....Vasoconstrictor</p> <p>Pramoxine HCl 1%.....Local anesthetic</p> <p>White petrolatum 15%.....Protectant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>for temporary relief of pain, soreness and burning</li> <li>helps relieve the local itching and discomfort associated with hemorrhoids</li> <li>temporarily shrinks hemorrhoidal tissue</li> </ul> <p><b>Directions</b></p> <p>Step use and ask a doctor if a 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</p> <p>If pregnant or breast-feeding, ask a doctor before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before applying cream • when first opening the tube, remove the foil seal</li> <li>apply externally or in the lower portion of the anal canal only</li> <li>apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement</li> <li>for application in the lower anal canal: remove cover from applicator. Attach applicator to tube. Lubricate applicator well, then gently insert applicator pathway into the anus.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Purpose</b></p> <ul style="list-style-type: none"> <li>temporarily provides a coating for relief of anal/rectal discomforts</li> <li>temporarily protects the inflamed, irritated anal/rectal surface to help make bowel movements less painful</li> </ul> <p><b>Warnings</b></p> <p>For external use only.</p> <p>Ask a doctor before use if you have • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland</p> <p>Ask a doctor before use if you are presently taking a prescription drug for high blood pressure or depression.</p> <p>When using this product • do not exceed the recommended daily dosage unless directed by a doctor</p> <p><b>Other Information</b> Store at 20°-25°C (68°-77°F).</p> <p><b>Inactive Ingredients</b> Aloe barbadensis leaf juice, Carbomer/methylcellulose sodium, Cetylalcohol, Light mineral oil, Methylparaben, Mono-and-di-glycerides, Polyethylene glycol, Propylparaben, Purified water, Stearic acid, Xanthan gum.</p> <p><b>Questions or Comments?</b> Call 1-888-286-9997</p> <p><b>Distributed by:</b> Trifecta Pharmaceuticals USA* 101 NE Third Avenue, Suite 1500 FL Lauderdale, FL 33301 USA www.trifecta-pharma.com</p>
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**Drug Facts (continued)**

• do not put into the rectum by using fingers or any mechanical device or applicator

Step use and ask a doctor if • a 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.

**Drug Facts (continued)**

• thoroughly cleanse applicator after each use and replace cover • children under 12 years of age: ask a doctor

**Other Information** Store at 20°-25°C (68°-77°F).

**Inactive Ingredients** Aloe barbadensis leaf juice, Carbomer/methylcellulose sodium, Cetylalcohol, Light mineral oil, Methylparaben, Mono-and-di-glycerides, Polyethylene glycol, Propylparaben, Purified water, Stearic acid, Xanthan gum.

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0 40232 62283 0



**HEMORRHOIDAL CREAM**  
**MAXIMUM STRENGTH PAIN RELIEF**

# INNER TUBE

**\*Compare to the active ingredients in Preparation H® Hemorrhoidal Cream**

NDC: 69396-171-18



**HEMORRHOIDAL CREAM**

**MAXIMUM STRENGTH PAIN RELIEF**

NET WT. 1.8 OZ. (51G)



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## HEMORRHOIDAL CREAM

glycerol, phenylephrine, pramoxine, petrolatum cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69396-171

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 100-200 MPAS AT 1%)</b> (UNII: 99H65D77XY)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<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)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69396-171-33	3 in 1 BOX	06/30/2025	
1		51 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-171-22	2 in 1 BOX	06/30/2025	
2		51 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69396-171-18	1 in 1 BOX	06/30/2025	
3		51 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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OTC Monograph Drug M015

06/30/2025

**Labeler** - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 7/2025

Trifecta Pharmaceuticals Usa Llc