

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

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 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

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 cleaning 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

Trouble 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)

Do not use if tube seal is broken or missing

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

Inactive Ingredients

Aloe barbadensis leaf juice, carboxymethylcellulose sodium, cetyl alcohol, glyceryl monostearate, methylparaben, 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

Product of PRC

www.trifecta-pharma.com

Packaging

OUTSIDE BOX




LOT:
EXP:

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



HEMORRHOIDAL CREAM

Maximum Strength Pain Relief

Net Wt. 1.8 oz. (51g)

NDC: 693


Smooth Cream with Aloe

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

Drug Facts	Drug Facts (continued)
<p>Active Ingredients</p> <p>Glycerol 14.4% Protectant</p> <p>Phenylephrine HCl 0.25% Vasoconstrictor</p> <p>Pramoxine HCl 1% Local anesthetic</p> <p>Petrolatum 16% Protectant</p> <p>Uses</p> <ul style="list-style-type: none"> ■ 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 <p>Warnings</p> <p>For external use only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ thyroid disease ■ diabetes ■ trouble urinating due to prostate gland <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</p> <ul style="list-style-type: none"> ■ 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 a suppository 	<p>Drug Facts (continued)</p> <p>Other Information</p> <p>Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive Ingredients</p> <p>Aloe barbadensis leaf juice, carboxymethylcellulose sodium, cetyl alcohol, monostearate, methylparaben, mineral oil, polysorbate 80, propylene glycol, propylparaben, purified water, stearic acid, xanthan gum</p> <p>Questions or Comments?</p> <p>Call 1-888-296-9067</p> <p>Directions</p> <p>■ 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</p> <p>■ when first opening tube, puncture foil seal with top end of cap</p> <p>■ apply externally or in the lower portion of the anal canal only</p> <p>■ apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement</p>

Trilecta Pharmaceuticals USA[®]


101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | Product of PRG | www.trilecta-pharma.com



0 40232 6228

INNER TUBE

COMPARE TO the active ingredients in PREPARATION H[®] HEMORRHOIDAL CREAM



HEMORRHOIDAL CREAM

Maximum Strength Pain Relief

Net Wt. 1.8 oz. (51g)

NDC: 69396-032-18

Smooth Cream with Aloe

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

Drug Facts	Drug Facts (continued)
<p>Active Ingredients</p> <p>Glycerol 14.4% Protectant</p> <p>Phenylephrine HCl 0.25% Vasoconstrictor</p> <p>Pramoxine HCl 1% Local anesthetic</p> <p>Petrolatum 16% Protectant</p> <p>Uses</p> <ul style="list-style-type: none"> ■ 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 <p>Warnings</p> <p>For external use only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland <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</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <p>Other Information</p> <p>Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive Ingredients</p> <p>Aloe barbadensis leaf juice, carboxymethylcellulose sodium, cetyl alcohol, glyceryl monostearate, methylparaben, mineral oil, polysorbate 80, propylene glycol, propylparaben, purified water, stearic acid, xanthan gum</p> <p>Questions or Comments?</p> <p>Call 1-888-296-9067</p> <p>Directions</p> <p>■ 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</p> <p>■ when first opening tube, puncture foil seal with top end of cap</p> <p>■ apply externally or in the lower portion of the anal canal only</p> <p>■ apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement</p>

Trilecta Pharmaceuticals USA[®]

101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | Product of PRG | www.trilecta-pharma.com

HEMORRHOIDAL CREAM

glycerol, phenylephrine, pramoxine, petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-033
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
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 100-200 MPA.S 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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-033-18	1 in 1 BOX	01/25/2019	
1		51 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
--------------------	--	----------------------	--------------------

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 1/2023

Trifecta Pharmaceuticals Usa Llc