

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

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, carboxymethylcellulose 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™

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1-888-296-9067

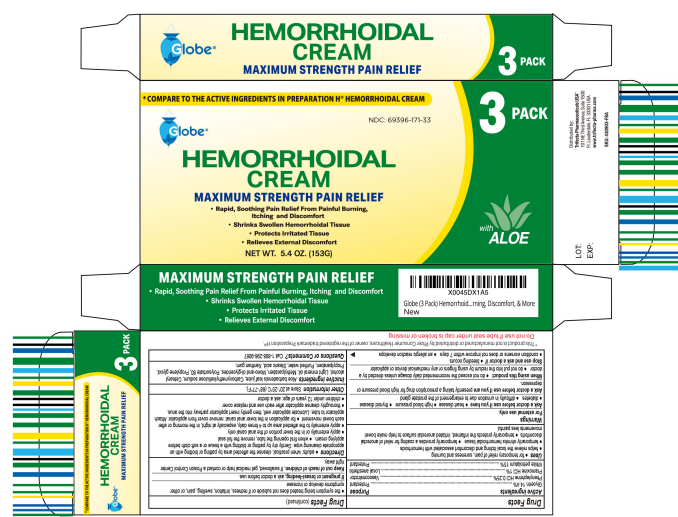
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SKU: 430903-FBA

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



HEMORRHOIDAL CREAM

glycerol, phenylephrine, pramoxine, petrolatum cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-171

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 100-200 MPA.S AT 1%) (UNII: 99H65D77XY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
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:69396-171-33	3 in 1 BOX	06/30/2025	
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
OTC Monograph Drug	M015	06/30/2025	

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)