HEMORRHOIDAL CREAM WITH ALOE- glycerol, phenylephine, 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 HCI 0.25%

Purpose

Vasoconstrictor

Active Ingredient

Pramoxine HCI 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 brfore 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 $H \otimes \mathbb{R}$

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.®

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Novi, MI.48375, USA

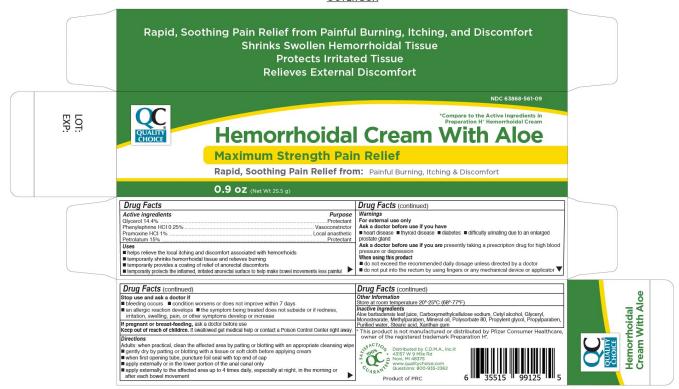
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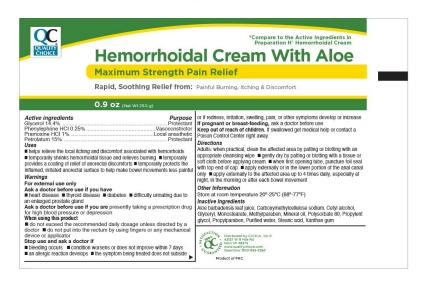
Product of PRC

Packaging

OUTER BOX



INNER TUBE



Hemorrhoidal Cream with Aloe

HEMORRHOIDAL CREAM WITH ALOE glycerol, phenylephine, pramoxine, petrolatum cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) 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 MPA.S AT 1%) (UNII: 99H65D77XY)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				
MINERAL OIL (UNII: T5L8T28FGP)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
XANTHAN GUM (UNII: TTV12P4NEE)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				

P	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)