HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hci ointment
Chain Drug Marketing Association Inc.

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.

Quality Choice Hemorrhoidal Ointment

Drug Facts

Active Ingredient

Phenylephrine HCl 0.25%

Purpose

Vasoconstrictor

Active Ingredient

Mineral Oil 14%

Purpose

Protectant

Active Ingredient

Petrolatum 74.9%

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

Warnings

For external and/or intrarectal use only

Ask doctor before use if you have

heart disease

high blood pressure

thyroid disease

diabetes

trouble urinating due to an enlarged prostate gland

Ask doctor before use if you are presently taking a prescription drug for high blood pressure.

Stop Use and Ask Doctor if

- Bleeding occurs
- Condition worsens or does not improve within 7 days
- Introduction of applicator into the rectum causes additional pain

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.

Ask doctor before use

Ask doctor before use if you are presently taking a prescription drug for high blood pressure.

Ask doctor before use if you have:

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Directions

- Adults and children 12 years of age and older for topical use:
- Clean the affected area and pat or dab dry before applying ointment.
- apply to the affected area up to 4 times daily, especially after each bowel movement.
- attach included applicator to tube
- lubricate applicator tip and gently insert into the rectum.
- thoroughly clean applicator after each use and replace cover.
- Children under 12 years of age; ask doctor before use

Other Information

- Store at room temperature 20º-25ºC (68º-77ºF)

Inactive Ingredients

Beeswax, Benzoic Acid, Cetyl alcohol, Glycerin, Methylparaben, Laureth-23, Propylparaben, Stearyl alcohol

Questions or Comments?

1-800-935-2362

Distributed By

Distributed By CDMA Inc.

43157 W 9 Mile Road

Novi, MI 48375

www.qualitychoice.com

Questions: 800-935-2362

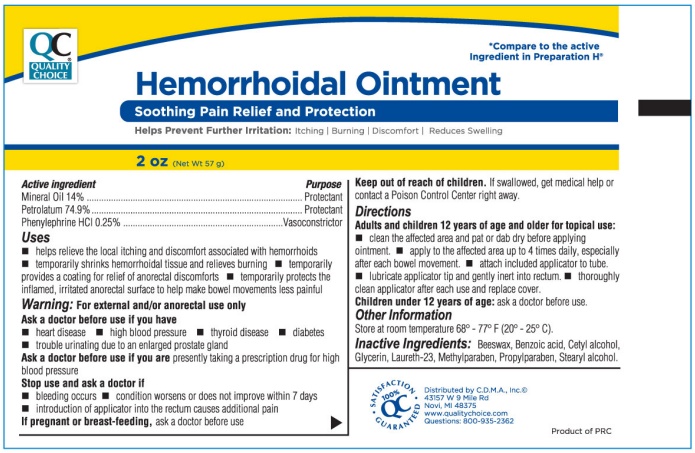
Product of PRC

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

Packaging

OUTSIDE BOX

INNER TUBE



HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hci ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-684
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

MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	74.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-23 (UNII: N72LMW566G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-684-02	1 in 1 BOX	08/14/2020	
1		57 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	08/14/2020	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 5/2023 Chain Drug Marketing Association Inc.