

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

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 20°-25°C (68°-77°F)

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

Drug Facts (continued) Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland Ask a doctor before use if you are presently taking a prescription drug for high blood pressure Stop use and ask a 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		Drug Facts (continued) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 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 rectum. ■ thoroughly clean applicator after each use and replace cover. Children under 12 years of age: ask a doctor before use.		LOT: EXP:
Drug Facts (continued) Other Information Store at room temperature 68° - 77° F (20° - 25° C). Inactive Ingredients: Beeswax, Benzoic acid, Cetyl alcohol, Glycerin, Laureth-23, Methylparaben, Propylparaben, Stearyl alcohol. <small>* This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Preparation H.</small>		Distributed by CDMA, Inc. Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362 		

NDC 83324-045-02

Hemorrhoidal Ointment
 Soothing Pain Relief and Protection
 Helps Prevent Further Irritation: Itching | Burning | Discomfort | Reduces Swelling

2 oz (Net Wt 57 g)

Drug Facts Active Ingredients Mineral Oil 14% Petrolatum 74.9% Phenylephrine HCl 0.25% Uses ■ helps relieve the local itching and discomfort associated with hemorrhoids		Drug Facts (continued) PurposeProtectantProtectantVasoconstrictor Warnings For external and/or anorectal use only	
Uses ■ 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 anorectal use only	

INNER TUBE

Drug Facts Active Ingredients Mineral Oil 14% Petrolatum 74.9% Phenylephrine HCl 0.25% 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 Warning: For external and/or anorectal use only Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland Ask a doctor before use if you are presently taking a prescription drug for high blood pressure Stop use and ask a 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		Drug Facts (continued) PurposeProtectantProtectantVasoconstrictor Warnings For external and/or anorectal use only	
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HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hci ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:83324-045

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:83324-045-02	1 in 1 BOX	05/14/2024	
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 Drug	M015	05/14/2024	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)