

HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hci ointment Rugby

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 or depression.

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.

Directions

- Children under 12 years of age; ask doctor before use
- 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.

- When first opening tube, remove foil seal
- Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.
- For intrarectal use: remove protective cover from applicator and attach to tube. Lubricate applicator well then gently insert applicator into the rectum. Thoroughly clean applicator and replace protective cover after each use.
- Regular use provides continual therapy for relief of symptoms
- also apply ointment to external area.

Other Information

- Store at room temperature 20°-25°C (68°-77°F)

Inactive Ingredients

Beeswax, Benzoic Acid, Cetyl alcohol, Glycerol Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, Stearyl alcohol

Distributed by:

Distributed by RUGBY® LABORATORIES

17177 N. Laurel Park Drive, Suite 233

Livonia, MI. 48152

www.rugbylaboratories.com

Made in China

This Product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Preparation H® Hemorrhoidal Ointment.

Questions or Comments?

1-800-645-2158

Packaging

OUTER BOX



INNER TUBE



HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hci ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1288	
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:0536-1288-06	1 in 1 BOX	05/14/2020	
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 Drug	M015		05/14/2020	

Labeler - Rugby (079246066)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)