

HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hci ointment

Rugby

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 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
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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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL PARABEN (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 final	part346	05/14/2020	

Labeler - Rugby (079246066)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)