

**HEMORRHOIDAL OINTMENT- mineral oil, petrolatum, phenylephrine
hcl ointment
Trifecta Pharmaceuticals USA LLC**

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 anorectal 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

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 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

Other Information

- Store at room temperature 20°-25°C (68°-77°F)
- Close cap tightly after use

Questions? Call 1-888-296-9067

Inactive Ingredients

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

Distributed By:

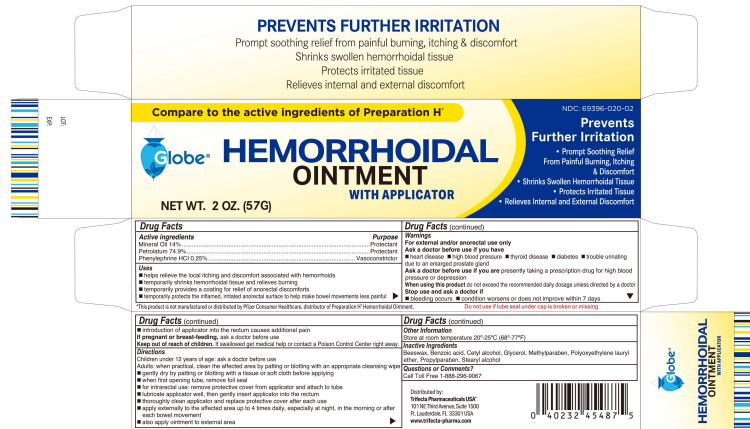
Trifecta Pharmaceuticals USA, LLC.®

101 NE Third Ave. Suite 1500

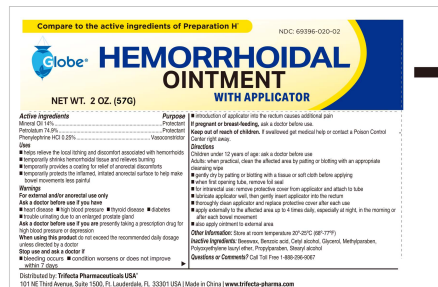
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OUTSIDE BOX



INNER TUBE



HEMORRHOIDAL OINTMENT

mineral oil, petrolatum, phenylephrine hci ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69396-020

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WHITE WAX (UNII: 7G1J5DA97F)	
THYME OIL (UNII: 2UK410MY6B)	
LANOLIN (UNII: 7EV65EAW6H)	
GLYCERIN (UNII: PDC6A3C0OX)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-020-02	1 in 1 BOX	05/04/2017	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-020-01	1 in 1 BOX	09/14/2020	
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69396-020-33	3 in 1 BOX	03/12/2024	
3		56 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:69396-020-44	4 in 1 BOX	03/12/2024	
4		56 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	05/04/2017	

