HEMORRHOIDAL OINTMENT- mineral oil, petrolatum, phenylephrine hci ointment
Trifecta Pharmaceuticals Usa Llc

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 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 Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

www.trifecta-pharma.com

Packaging

OUTER BOX

Globe®

COMPARE TO THE
ACTIVE INGREDIENT
IN PREPARATION H®
HEMORRHOID OINTMENT

NDC: 69396-020-05

Fast Relief from Hemorrhoids

Helps relieve the local itching and discomfort associated with hemorrhoids

NDC: 69396-020-05

HEMORRHOIDAL OINTMENT

Net Wt. 0.5oz. (15g)

- Quick soothing relief from the internal and external itching, burning, and discomfort of hemorrhoids
- Shrinks and protects irritated and swollen hemorrhoidal tissue
- Applicator included in carton

HEMORRHOIDAL OINTMENT

Globe®

100% GUARANTEED

0 40232 45494 3

Distributed by:
Trifecta Pharmaceuticals USA®
101 NE Third Avenue, Suite 1500
Ft. Lauderdale, FL 33301 USA
Product of PRC
www.trifecta-pharma.com

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

LOT:
EXP: 4/2019

Drug Facts

Active Ingredients	Purpose
Mineral Oil 14%	Protectant
Petrolatum 74.9%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor

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 a doctor before use if you have
- high blood pressure ■ thyroid disease
- heart 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

Drug Facts (continued)

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 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

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

Inactive Ingredients
Beeswax, Benzoic acid, Cetyl alcohol, Glycerol, Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, Stearyl alcohol

Questions?
Call 1-888-296-9067

NDC: 69396-020-05

Globe®

HEMORRHOIDAL OINTMENT

Net Wt. 0.5oz. (15g)

Active Ingredients	Purpose
Mineral Oil 14%	Protectant
Petrolatum 74.9%	Protectant
Phenylephrine HCl0 25%	Vasoconstrictor

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 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

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

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

Inactive Ingredients: Beeswax, Benzoic acid, Cetyl alcohol, Glycerol, Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, Stearyl alcohol

Questions? Call 1-888-296-9067

Distributed by: Trifecta Pharmaceuticals USA®
101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | Product of PRC | www.trifecta-pharma.com

HEMORRHOIDALOINTMENT

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-020-05	1 in 1 BOX	12/29/2016	
1		15 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	12/29/2016	

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 11/2017

Trifecta Pharmaceuticals Usa Llc