

# **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.*

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## **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

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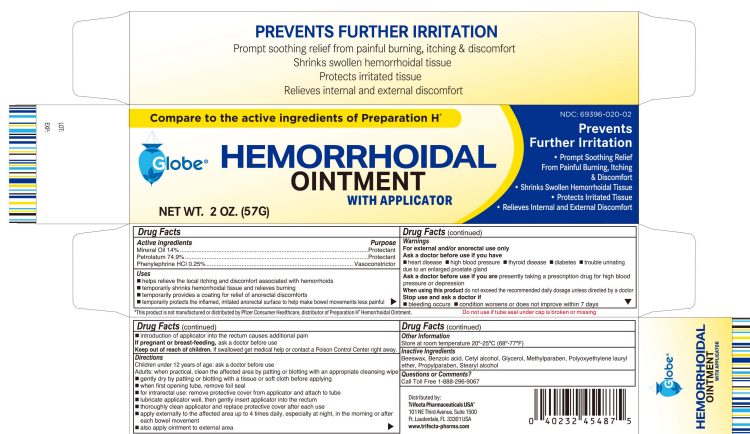
Trifecta Pharmaceuticals USA, LLC.®

101 NE Third Ave. Suite 1500

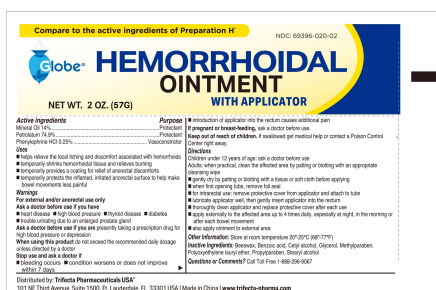
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OUTSIDE BOX



INNER TUBE



HEMORRHOIDAL OINTMENT

mineral oil, petrolatum, phenylephrine hci ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-020
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	74.9 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

**Inactive Ingredients**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part346	05/04/2017	

**Labeler** - Trifecta Pharmaceuticals USA LLC (079424163)