# HEMORRHOIDALOINTMENT- mineral oil, petrolatum, phenylephrine hci ointment Pharmacy Value Alliance, 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 HCI 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 or depression

When using this product do not exceed the recommended daily dosage unless directed by a doctor

### 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 a 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
- for intrarectal use: remove protective cover from applicator into the rectum
- lubricate applicator well, then gently insert applicator into the rectum
- thoroughly clean applicator and replace protective cover after each use
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- also apply ointment to external area

#### Other Information

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

### **Inactive Ingredients**

Beeswax, benzolc acid, Cetyl alcohol, Glycerol, Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, stearyl alcohol

## Distributed by:

Pharmacy Value Alliance, LLC. 407 East Lancaster Avenue Wayne, PA. 19087 www.emersongroup.com

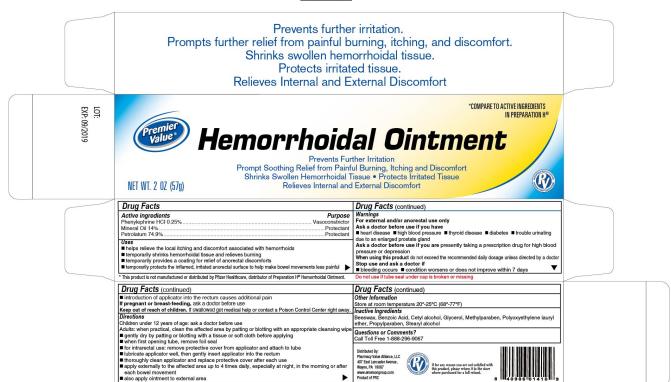
Product of PRC

### **Hemorrhoidal Ointment**

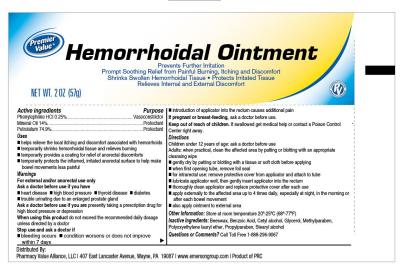
- Prevents Further Irritation
- Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal and External Discomfort

## **Packaging**

#### **OUTER BOX**



#### **INNER TUBE**



#### **HEMORRHOIDALOINTMENT**

mineral oil, petrolatum, phenylephrine hci ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-528
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
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
THYME OIL (UNII: 2UK410MY6B)	
WHITE WAX (UNII: 7G1J5DA97F)	
PARAFFIN (UNII: 1900E3H2ZE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68016-528- 00	1 in 1 BOX	07/19/2016		
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	07/19/2016		

# Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 3/2023 Pharmacy Value Alliance, LLC