

**HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hci ointment**  
**Cardinal Health 110 dba LEADER**

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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 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 (1-800-222-1222) 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 Cardinal Health**

Dublin, Ohio 43017

**www.myleader.com**

**1-800-200-6313**

**Essential to Care™ since 1979**

**Made in China**

**Questions or Comments?**

**1-888-296-9067**

**Packaging**

OUTER BOX



## INNER TUBE

NDC 70000-0046-1

**Hemorrhoidal Ointment**  
**With Applicator**

**COMPARE TO PREPARATION H<sup>®</sup> HEMORRHOIDAL OINTMENT**  
**active ingredients\***

100% Money Back Guarantee

**NET WT 2 OZ (57 g)**

Prevents Further Irritation

**Active ingredients**  
Mineral Oil 14%  
Petrolatum 74.9%  
Phenylephrine HCl 0.25%

**Purpose**  
Protectant  
Protectant  
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 intrarectal 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 or pharmacist 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 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 (1-800-222-1222) 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  
■ 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  
**Questions or comments?** 1-888-296-9067

**DO NOT USE IF TUBE SEAL UNDER CAP IS BROKEN OR MISSING**

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\*This product is not manufactured or distributed by Prior Consumer Healthcare, distributor of Preparation H<sup>®</sup> Hemorrhoidal Ointment.    Return to place of purchase if not satisfied.    REV. 4/20

# HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hci ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0046
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	

LAURETH-23 (UNII: N72LMW566G)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0046-1	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 Drug		M015	05/14/2020	

**Labeler** - Cardinal Health 110 dba LEADER (063997360)

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

Revised: 1/2024

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