

**HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hci ointment**  
**Cardinal Health 100, Inc.**

*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 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 7000-0046-1

**LEADER**<sup>™</sup>

## Hemorrhoidal Ointment With Applicator

Prevents Further Irritation

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

100% Money Back Guarantee

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

**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

**Directions**  
■ 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**  
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■ 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.  
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**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**

DISTRIBUTED BY: CARDINAL HEALTH, DUBLIN, OHIO 43017    Made in China    www.myleader.com    1-800-200-6313    ©2020 Cardinal Health    100% Money Back Guarantee    CIN 5599949  
\*This product is not manufactured or distributed by Pfizer 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
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
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETYL ALCOHOL (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 final	part346	05/14/2020	

**Labeler** - Cardinal Health 100, Inc. (097537435)

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

Revised: 5/2020

Cardinal Health 100, Inc.