

**FREDS HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hydrochloride cream  
Fred's, 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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**Fred's Hemorrhoidal Ointment 2oz w/applicator NBE Preparation H**

<b>Active Ingredients</b>	<b>Purpose</b>
Mineral Oil 14%.....	Protectant
Petrolatum 74.9%.....	Protectant
Phenylephrine Hydrochloride 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 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** now taking a prescription drug for high blood pressure or depression

**Stop use and ask a doctor if:**

- bleeding occurs
- condition gets worse or does not get better within 7 days
- introduction of the applicator into the rectum causes additional pain

**If pregnant or breast-feeding,** ask a physician 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
- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe
- gently dry by patting or blotting with a tissue or a soft cloth before applying
- when first opening tube, remove foil seal
- **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
- 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 20° to 25°C (68° to 77°F)

**Inactive Ingredients**

glycerin, lanolin, methylparaben, propylparaben, steryl alcohol, thyme oil, tocopherol acetate, water, white wax

**DISTRIBUTED BY:**

FRED'S, INC.

4300 NEW GETWELL RD.

MEMPHIS, TN 38118 USA

**Drug Facts** (continued)

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 now taking a prescription drug for high blood pressure or depression

When using this product do not use more than the recommended daily dosage

Stop use and ask a doctor if  bleeding occurs  condition gets worse or does not get better within 7 days  introduction of the applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a physician before use. ▶

**Drug Facts** (continued)

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  adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe  gently dry by patting or blotting with a tissue or a soft cloth before applying  when first opening tube, remove foil seal  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

DISTRIBUTED BY: fred's, Inc.  
4300 NEW GETWELL RD, MEMPHIS, TN 38118  
www.fredsinc.com

Made in Korea



0 84579 18677 8

**fred's** Promise  
Not Happy With This Product?  
Just Bring It Back For a Refund!

\*This product is not manufactured or distributed by Pizer Consumer Healthcare, owner of the registered trademark Preparation H®.

LOT:  
EXP:



**Hemorrhoidal Ointment**  
With Applicator  
NET WT 2 OZ (57g)

Soothing Relief from Painful Burning,  
Itching and Discomfort Associated  
with Hemorrhoids



(RETAIN CARTON FOR COMPLETE LABEL INFORMATION)

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**FREDS HEMORRHOIDAL**

mineral oil, petrolatum, phenylephrine hydrochloride cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-336
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g

<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		<b>PHENYLEPHRINE HYDROCHLORIDE</b>	2.5 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)				
LANOLIN (UNII: 7EV65EAW6H)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
STEARYL ALCOHOL (UNII: 2KR89I4HIY)				
THYME OIL (UNII: 2UK410MY6B)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0K00R)				
WHITE WAX (UNII: 7G1J5DA97F)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55315-336-57	1 in 1 BOX	10/06/2016	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<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	01/03/2014		

**Labeler** - Freds, Inc (005866116)

Revised: 12/2017

Freds, Inc