

HEMORRHOIDAL OINTMENT- 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.

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 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

Prevents further irritation.
Prompts further relief from painful burning, itching, and discomfort.
Shrinks swollen hemorrhoidal tissue.
Protects irritated tissue.
Relieves Internal and External Discomfort

*COMPARE TO ACTIVE INGREDIENTS
IN PREPARATION H®

Premier Value®
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

NET WT. 2 OZ (57g)

LOT: 6
EXP: 09/2019

<p>Drug Facts</p> <p>Active Ingredients</p> <p>Phenylephrine HCl 0.25%.....Vasoconstrictor Mineral Oil 14%.....Protectant Petrolatum 74.9%.....Protectant</p> <p>Purpose</p> <p>Protectant</p> <p>Uses</p> <ul style="list-style-type: none"> 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 <p>* This product is not manufactured or distributed by Pfizer Healthcare, distributor of Preparation H® Hemorrhoidal Ointment.</p>	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>For external and/or anorectal use only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease high blood pressure thyroid disease diabetes trouble urinating due to an enlarged prostate gland <p>Ask a doctor before use if you are presently taking a prescription drug for high blood pressure or depression</p> <p>When using this product do not exceed the recommended daily dosage unless directed by a doctor</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> bleeding occurs condition worsens or does not improve within 7 days <p>Do not use if tube seal under cap is broken or missing</p>
<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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. <p>Directions</p> <p>Children under 12 years of age: ask a doctor before use</p> <p>Adults: when practical, clean the affected area by patting or blotting with an appropriate cleansing wipe</p> <ul style="list-style-type: none"> 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 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 	<p>Drug Facts (continued)</p> <p>Other Information</p> <p>Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive Ingredients</p> <p>Beeswax, Benzoic Acid, Cetyl alcohol, Glycerol, Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, Stearyl alcohol</p> <p>Questions or Comments?</p> <p>Call Toll Free 1-888-296-9067</p> <p>Distributed By: Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19087 www.emersongroup.com Product of PRC</p> 

INNER TUBE

Premier Value®
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

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HEMORRHOIDAL OINTMENT

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: Z8IX2SC1OH)	
THYME OIL (UNII: 2UK410MY6B)	
WHITE WAX (UNII: 7G1J5DA97F)	
PARAFFIN (UNII: I9O0E3H2ZE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

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