

HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine ointment

Geritrex 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

Active Ingredient	Purpose
Mineral Oil - 14%	Protectant
Petrolatum - 71.9%	Protectant
Phenylephrine - 0.25%	Astringent

Uses:

- Helps relieve local itching and discomfort with hemorrhoids.
- Temporarily shrinks hemorrhoid tissues 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
- Thyroid disease
- Diabetes
- High Blood pressure
- Difficulty in urination due to enlargement of the prostate gland

Ask a doctor or a 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 the applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

If swallowed get medical help or contact a poison control center right away.

Directions:

- Adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing tissue.
- Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this ointment
- Apply to affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.

For Intrarectal use

- Remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert into the rectum.
- Thoroughly cleanse applicator after each use
- Also apply ointment to external area
- Regular use provides continual therapy for relief of symptoms
- Children under 12 years of age, consult a doctor

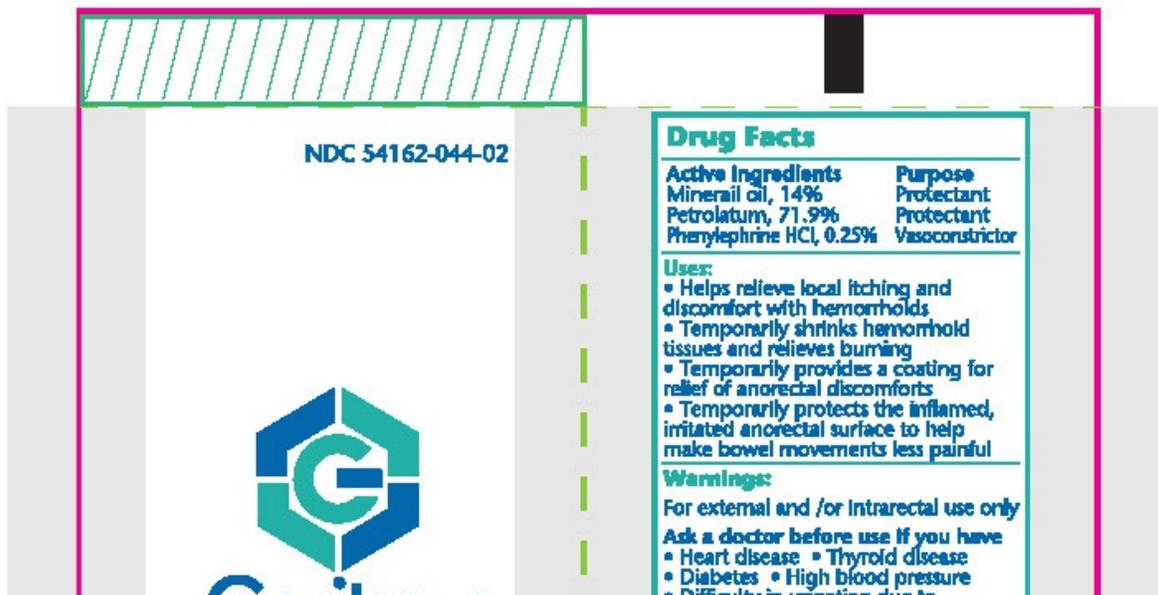
Other Information:

Store at room temperature but not over 80° F

Lot No. & Exp Date: See tube

Inactive Ingredients:

Beeswax, benzoic acid, BHA, corn oil, glycern, lanolin alcohol, methyparaben, paraffin, propylparaben, shark liver oil, thyme, tocopherol, water.



Geritrex®

GR^x
**Hemorrhoidal
Ointment**

**Temporarily Relieves
Itching, Burning
and Discomfort
of Hemorrhoids**

NET WT 2 OZ 57g

• Caution: In rare cases use may cause enlargement of the prostate gland
Ask a doctor or a pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression

When using this product
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• Conditions worsens or does not improve within 7 days
• Introduction of the applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a health professional before use.

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• Lot No. & Exp. Date: See tube

Inactive Ingredients:
Beeswax, benzoic acid, BHA, cam oil, glycerin, lanolin alcohol, methyl paraben, paraffin, propyl paraben, shark liver oil, thyme, tocopherol, water



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HEMORRHOIDAL

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Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54162-044

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	7.98 g in 57 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	40.983 g in 57 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.1425 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CORN OIL (UNII: 8470G57WFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHARK LIVER OIL (UNII: 4B24275HEU)	
THYME (UNII: CW6570BU4N)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-044-02	57 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/31/2015	

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-044)