

HEMORRHOIDAL OINTMENT- mineral oil, petrolatum, phenylephrine hci ointment

Trifecta Pharmaceuticals USA 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.

Best Choice 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
- Introduction of applicator into the rectum causes additional pain

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

Stop Use and Ask Doctor if

- Bleeding occurs
- Condition worsens or does not improve within 7 days

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

When using this product

When using this product do not exceed the recommended dosage unless directed by a doctor

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 and attach to tube
- Lubricate applicator well, then gently insert applicator into rectum
- Thoroughly clean applicator and replace protective cover after each use
- Clean the affected area and pat or dab dry before applying ointment
- 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, Benzoic Acid, Cetyl alcohol, Glycerol Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, Stearyl alcohol

Questions

Call 1-800-883-0085

Distributed By

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Call 1 844 2921112 for product information

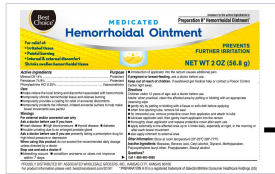
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OUTSIDE BOX



INNER TUBE



HEMORRHOIDAL OINTMENT

mineral oil, petrolatum, phenylephrine hci ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		1.1 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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-15 (UNII: 002FR4N8OV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-133-20	1 in 1 BOX	06/01/2023	
1		56.8 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	06/01/2023	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 6/2023

Trifecta Pharmaceuticals USA LLC