

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.

CVS 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
- difficulty in urination due to enlargement of the 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).

Directions

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 ointment.
- Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.
- Intrarectal Use: remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum, thoroughly cleanse applicator after each use and replace cover.
- Also apply ointment to external area
- Regular use provides continual therapy for relief of symptoms
- Children under 12 years of age: ask a doctor

Other Information

- Store at room temperature 20°-25°C (68°-77°F)
- Do not use if tube seal is broken or missing

Questions? Call 1-888-296-9067

Inactive Ingredients

Beeswax, Benzoic Acid, Cetyl alcohol, Glycerol Methylparaben, Polyoxyethylene lauryl ether, Propylparaben, Stearyl alcohol

Other Information

Distributed By:

CVS Pharmacy Inc.

One CVS Drive

Woodsocket, RI 02895

CVS.com

1 800 SHOP CVS

Made in China

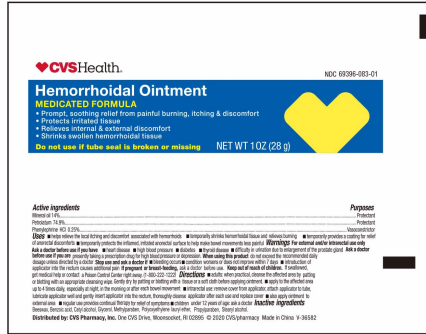
V36582

Packaging

OUTSIDE BOX



INNER TUBE



HEMORRHOIDAL OINTMENT

mineral oil, petrolatum, phenylephrine hci ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
LAURETH-23 (UNII: N72LMW566G)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-083-01	1 in 1 BOX	06/28/2021	
1		28 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	06/28/2021	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 1/2023

Trifecta Pharmaceuticals USA LLC