

HEMORRHOIDAL - mineral oil,petrolatum,phenylephrine ointment
Navarro Discount Pharmacies,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.

Drug Facts

Active ingredients

Mineral oil 14%

Petrolatum 71.9%

Phenylephrine HCl 0.25%

Purpose

Protectant

Protectant

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
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or 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 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 wipe. Gently dry by patting or blotting with a tissue or a soft cloth before applying ointment.
- when first opening tube, puncture foil seal with top end of cap
- 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 form 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

Other information

Store at 20° to 25°C (68° to 77°F)

Inactive ingredients

bees wax, butylated hydroxytoluene, cod liver oil, glycerin, lanolin, methylparaben, paraffin wax, propylparaben, purified water, sodium benzoate, squalane, thyme oil, tocopherol acetate

Package label

Vida Mia Hemorrhoidal Ointment



HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59970-049
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	71.9 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COD LIVER OIL (UNII: BBL281NWFG)	

GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
THYME OIL (UNII: 2UK410MY6B)	
APIS MELLIFERA (UNII: 7S82P3R43Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59970-049-02	1 in 1 CARTON		
1		57 g in 1 TUBE		
2	NDC:59970-049-01	1 in 1 CARTON		
2		28 g in 1 TUBE		
3	NDC:59970-049-05	1 in 1 CARTON		
3		19 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	08/13/2012	

Labeler - Navarro Discount Pharmacies,LLC (094930963)

Revised: 8/2012

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