

MINERAL OIL, PETROLATUM AND PHENYLEPHRINE HCL- mineral oil, petrolatum, phenylephrine hcl ointment
Axcentria Pharmaceuticals, 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 INGREDIENTS

Mineral oil 14%

Petrolatum 71.9%

Phenylephrine HCl 0.25%

PURPOSES

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 the 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 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
- children under 12 years of age: ask a doctor

OTHER INFORMATION

store at 20-25°C (68-77°F)

INACTIVE INGREDIENTS

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, shark liver oil, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax

QUESTIONS?

To report adverse drug event call: (800) 616-2417

PRINCIPAL DISPLAY PANEL - 56.8 g Tube Carton

**HEMORRHOIDAL
OINTMENT**

TAMPER-EVIDENT: Do not use if printed "safety sealed" overwrap is broken or missing.

- 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 (56.8 g)



MINERAL OIL, PETROLATUM AND PHENYLEPHRINE HCL

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49 743-3047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	741 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MM)	

BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)
CORN OIL (UNII: 8470G57WFM)
GLYCERIN (UNII: PDC6A3C0OX)
LANOLIN (UNII: 7EV65EAW6H)
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)
METHYLPARABEN (UNII: A2I8C7HI9T)
PARAFFIN (UNII: I9O0E3H2ZE)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0K00R)
SHARK LIVER OIL (UNII: 4B24275HEU)
THYME (UNII: CW6570BU4N)
TOCOPHEROL (UNII: R0ZB2556P8)
WHITE WAX (UNII: 7G1J5DA97F)

Product Characteristics			
Color	YELLOW (smooth yellow ointment)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49743-3047-1	1 in 1 CARTON		
1		56.8 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	06/28/2013	

Labeler - Axcentria Pharmaceuticals, LLC (961871501)

Establishment			
Name	Address	ID/FEI	Business Operations
Axcentria Pharmaceuticals, LLC		961871501	ANALYSIS(49743-3047) , MANUFACTURE(49743-3047)