

FAMILY CARE HEMORRHOIDAL- mineral oil ointment

United Exchange Corp

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.

Family Care Hemorrhoidal Ointment 0.67oz (with applicator) 515, 2019

Active ingredients	Purpose
Mineral oil 14%.....	Protectant
Petrolatum 74.9%.....	Protectant
Phenylephrine HCl 0.25%.....	Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieve 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 use only / or intrarectal use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Ask a doctor or a pharmacist before use if you are now taking a prescription drug for high blood pressure or depression

When using this product do not use more than the recommended daily dosage unless directed by a doctor

Stop use and ask a doctor if

- bleeding occurs
- condition gets worse or does not get better within 7 days

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- children under 12 years of age: ask a doctor
- 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, remove foil seal
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for intraeatal use: remove protective cover from applicator and attach applicator to tube
- lubricate applicator well, then gently insert applicator into the rectum

- thoroughly clean applicator and replace protective cover after each use
- also apply ointment to external area
- regular use provides continual therapy for relief of symptoms

Other information

- store at 20° C to 25°C (68° to 77°F)
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients glycerin, lanolin, methylparaben, propylparaben, stearyl alcohol, thyme oil, tocopherol acetate, water, white wax

Distributed by:

United Exchange Corp

17211 Valley View Ave.

Cerritos, CA 90703 USA

Made in Korea



FAMILY CARE HEMORRHOIDAL

mineral oil ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65923-003

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 100 g	
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)		PETROLATUM	749 mg in 100 g	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
LANOLIN (UNII: 7EV65EAW6H)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
STEARYL ALCOHOL (UNII: 2KR89I4HIY)				
THYME OIL (UNII: 2UK410MY6B)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
WHITE WAX (UNII: 7G1J5DA97F)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-003-20	1 in 1 CARTON	11/24/2014	
1		20 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		11/24/2014	

Labeler - United Exchange Corp (840130579)