

SHOPKO 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.

Drug Facts

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 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
- trouble urinating due to an enlarged prostate gland

Ask a doctor or 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

Stop use and ask a doctor if

- bleeding occurs
- condition gets worse or does not get better within 7 days
- introduction of the applicator into the rectum causes additional pain

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
- 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 the rectum
- thoroughly clean applicator and replace protective cover after each use
- 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 20° to 25°C (68° to 77°F)

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

Made in Korea



SHOPKO HEMORRHOIDAL			
mineral oil ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-778
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: 2KR89I4H1Y)	
THYME OIL (UNII: 2UK410MY6B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-778-57	1 in 1 CARTON		
1		57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/30/2013	

Labeler - United Exchange Corp (840130579)

Revised: 6/2013

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