

TOPCARE HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hcl ointment
Topco Associates 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.

Topco Associates LLC. Hemorrhoidal Ointment Drug Facts

Active ingredients

Mineral oil 14%

Petrolatum 74.9%

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. (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.
- 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
- regular use provides continual therapy for relief of symptoms
- children under 12 years of age: ask a doctor

Other information

- store at 20-25°C (68-77°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

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

MEDICATED

Hemorrhoidal Ointment

PREVENTS FURTHER IRRITATION

Prompt, soothing relief from painful burning, itching and discomfort

Shrinks swollen hemorrhoidal tissue

Protects irritated tissue

Relieves internal and external discomfort

COMPARE TO PREPARATION H® HEMORRHOIDAL OINTMENT active ingredients



TOPCARE HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-188
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140.000 mg in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749.000 mg in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.500 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

COD LIVER OIL (UNII: BBL281NWFQ)
GLYCERIN (UNII: PDC6A3C0OX)
LANOLIN (UNII: 7EV65EAW6H)
METHYLPARABEN (UNII: A2I8C7HI9T)
PARAFFIN (UNII: I9O0E3H2ZE)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0K00R)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SQUALANE (UNII: GW89575KF9)
THYME OIL (UNII: 2UK410MY6B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-188-16	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	07/22/2013	

Labeler - Topco Associates LLC (006935977)