# 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

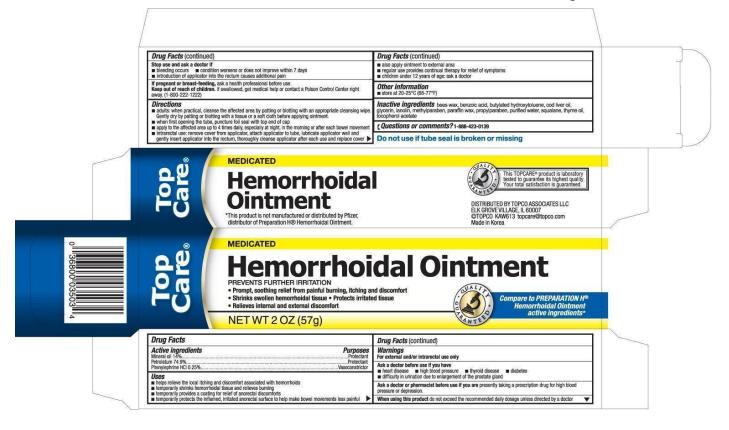
Prompt, soothing relief from painful burning, itching and discomfort

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**

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-188 **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
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.500 mg in 100 g

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	

COD LIVER OIL (UNII: BBL281NWFG)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E )	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SQUALANE (UNII: GW89575KF9)	
THYME OIL (UNII: 2UK410 MY6 B)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics			
Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

F	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)

Revised: 8/2013 Topco Associates LLC