TOPCARE HEMORRHOIDAL- mineral oil, petrolatum and phenylephrine hydrochloride 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 71.9%

Phenylephrine HCl 0.25%

Purposes

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

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, shark liver oil, thymus vulgaris (thyme) oil, tocopheryl acetate, white wax

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

MEDICATED Hemorrhoidal Ointment

PREVENTS FURTHER IRRITATION

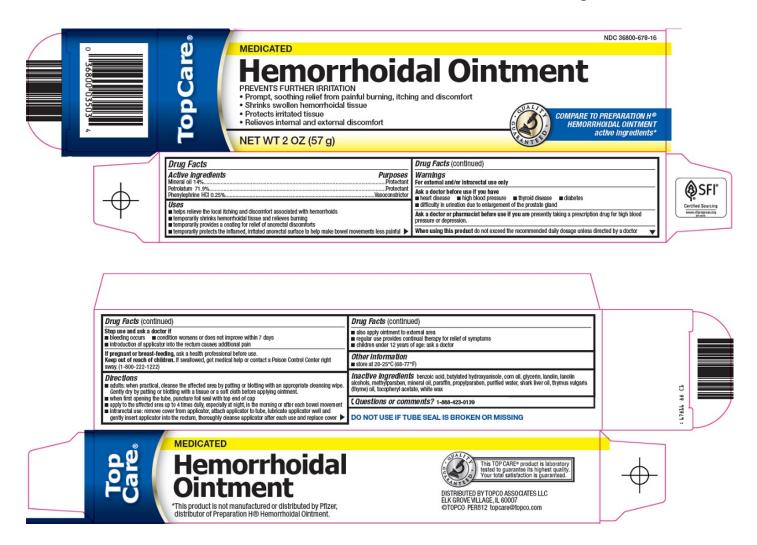
Prompt, soothing relief from painful burning, itching and discomfort

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 LABEL	Item Code (Source)	NDC:36800-678
Route of Administration	RECTAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MINERAL OIL (MINERAL OIL)	MINERAL OIL	140.000 mg in 100 g	
PETROLATUM (PETROLATUM)	PETROLATUM	719.000 mg in 100 g	
PHENYLEPHRINE HYDRO CHLO RIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	2.500 mg in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
BENZOIC ACID		
BUTYLATED HYDRO XYANISOLE		
CORN OIL		
GLYCERIN		
LANOLIN		
LANOLIN ALCOHOLS		
METHYLPARABEN		
PARAFFIN		
PROPYLPARABEN		
WATER		
SHARK LIVER OIL		
THYME O IL		
ALPHATO CO PHERO L ACETATE		
WHITE WAX		

Product Characteristics			
Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-678-16	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	12/07/2012		

Labeler - Topco Associates LLC (006935977)

Revised: 2/2013 Topco Associates LLC