# HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine ointment Valu Merchandisers, Co.

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.

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#### **Best Choice Hemorrhoidal Ointment**

#### 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 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

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.

#### 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 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 form applicator and attach tube, lubricate applicator well, then 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

Other information

Store at 20 ° to 25 °C (68 ° to 77 °F)

#### **Inactive ingredients**

beeswax, benzoic acid, BHT, cocoa butter, cod liver oil, glycerin, lanolin, methylparaben, paraffin, propylparaben, purified water, squalane, thyme oil, tocopherol acetate

# **Active ingredients**

Mineral oil 14%

Petrolatum 71.9%

Phenylephrine HCL 0.25%

#### Purpose

**Protectant** 

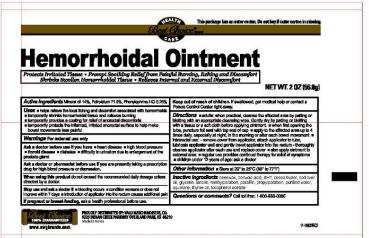
**Protectant** 

Vasoconstrictor

# Package label

Best Choice Hemorrhoidal Ointment





#### HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine ointment

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:63941-161

Route of Administration TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	71.9 g in 100 g
	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
APIS MELLIFERA (UNII: 7S82P3R43Z)		
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
COCOA BUTTER (UNII: 5120 YT1CRR)		
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)		
SQUALENE (UNII: 7QWM220FJH)		
THYME OIL (UNII: 2UK410 MY6 B)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:63941-161-02	1 in 1 CARTON	05/30/2018			
1	57 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	02/06/2012			

# Labeler - Valu Merchandisers, Co. (868703513)

Revised: 5/2018 Valu Merchandisers, Co.