

## **MAJOR PREP HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hcl ointment**

### **Major Pharmaceuticals**

*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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### **Major Pharmaceuticals Major-Prep Drug Facts**

#### **Active ingredients**

Mineral oil 14%

Petrolatum 74.9%

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, thymus vulgaris (thyme) oil, tocopheryl acetate, white wax

**Questions or comments?**

1-800-616-2471

**Package/Label Principal Display Panel**

Compare to Preparation H® Ointment active ingredients

MAJOR-PREP™

Hemorrhoidal Ointment

With Applicator

NET WT 2 OZ (57 g)



## MAJOR PREP HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hcl ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6726
<b>Route of Administration</b>	RECTAL		

### 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	74.9 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	.25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CORN OIL (UNII: 8470G57WFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	

<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>THYME OIL</b> (UNII: 2UK410MY6B)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

**Product Characteristics**

<b>Color</b>	YELLOW (light)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6726-02	1 in 1 CARTON	09/06/2018	
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	09/06/2018	

**Labeler - Major Pharmaceuticals (191427277)**