

**HEMORRHOIDAL - mineral oil, petrolatum, phenylephrine ointment**  
**Kareway Product, Inc.**

*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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**Drug Facts**

**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**

benzoic acid, butylated hydroxanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, shark liver oil, thyme oil, tocopherols excipient, white wax

### **Active ingredients**

Mineral oil 14%

Petrolatum 71.9%

Phenylephrine HCL 0.25%

### **Purpose**

Protectant

Protectant

Vasoconstrictor

### **Package label**

Pure-Aid Hemorrhoidal Ointment

Prompt Soothing Relief

NDC No. 67678-0056-4  
**Pure-Aid™**

- Prevents further irritation
- Soothing relief from burning, itching and discomfort
- Shrinks swollen hemorrhoidal tissue

Compare to the active ingredients of Preparation H® Hemorrhoidal Ointment\*



Prompt Soothing Relief

OINTMENT

# Hemorrhoidal

Prompt Soothing Relief

OINTMENT

# Hemorrhoidal

NET 0.67 oz(19g)

OINTMENT  
**Hemorrhoidal**

OINTMENT

# Hemorrhoidal



LOT & EXP.

**Drug Facts**

**Active Ingredients**  
 Mineral oil 14%  
 Petrolatum 71.9%  
 Phenylephrine HCl 0.25%  
 Vasoconstrictor

**Purpose**  
 Protectant

**Uses**  
 ■ helps relieve the local itching and discomfort associated with hemorrhoids  
 ■ temporarily shrinks hemorrhoidal tissue and relieves burning  
 ■ temporarily provides relief for anal or rectal discomforts  
 ■ temporarily protects the inflamed, irritated anal or rectal 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

**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 soft cloth before applying ointment.  
 ■ when first opening the tube, puncture foil seal with top end of cap or by using a sharp object.  
 ■ 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° to 25°C (68° to 77°F).

**Inactive ingredients**  
 benzocaine, butylated hydroxyanisole, camphor, glycerin, lanolin, lanolin alcohol, methylparaben, mineral oil, petrolatum, propylparaben, purified water, shark liver oil, thymol, thymus vulgaris (thyme) flower/leaf oil, tocopherol, white wax.

**Exclusively distributed by:**  
 Kareway Product Inc. Compton, CA 90220  
 Made in Korea

**Hemorrhoidal OINTMENT** **KAREWAY**

## HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine ointment

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67510-0056

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	14 g in 100 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	71.9 g in 100 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>LANOLIN ALCOHOLS</b> (UNII: 884C3FA9HE)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SHARK LIVER OIL</b> (UNII: 4B24275HEU)	
<b>THYME OIL</b> (UNII: 2UK410MY6B)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0056-2	1 in 1 CARTON		
1		57 g in 1 TUBE		
2	NDC:67510-0056-1	1 in 1 CARTON		
2		28 g in 1 TUBE		
3	NDC:67510-0056-6	1 in 1 CARTON		
3		19 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/02/2012	

**Labeler** - Kareway Product, Inc. (121840057)