

**AVEDANA HEMORRHOIDAL PAIN RELIEF- mineral oil, petrolatum,  
phenylephrine hcl ointment  
Unipack 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.*

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**Avedana® Hemorrhoidal Pain Relief Ointment**

**(Mineral Oil, Petrolatum and Phenylephrine HCl)**

**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.

**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 15°C - 30°C (59°F -86°F)

**INACTIVE INGREDIENTS**

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax

**QUESTIONS OR COMMENTS?**

Call weekdays 9 AM to 5 PM EST at **1-724-733-7381**

## PRINCIPAL DISPLAY PANEL - 57 g Tube Label

THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.

Avedana<sup>®</sup>  
HEMORRHOIDAL PAIN RELIEF 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

NET WT 2 OZ (57 g)

HEMORRHOIDAL  
**Pain Relief Ointment**

**Avedana<sup>®</sup>**  
...means no pain!

NDC 43749-480-04

**PREVENTS FURTHER IRRITATION** **PROTECTS IRRITATED TISSUE** **OINTMENT**

- Prompt, soothing relief from painful burning, itching & discomfort
- Shrinks swollen hemorrhoidal tissue
- Relieves internal & external discomfort

NET WT 2 OZ (57 g)

**Active Ingredients** Mineral Oil 14%, Petrolatum 74.9%, Phenylephrine HCl 0.25%

**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.

**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 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 the temp. should be (15° C - 30° C, 59° F - 86° F)  
**Inactive ingredients** benzoic acid, butylated hydroxytoluene, corn oil, glycerin, lanolin, lanolin alcohol, methylparaben, propylparaben, paraffin wax, purified water, thymus vulgaris oil, tocopherol acetate, white wax

**MANUFACTURED BY:**  
UNIPACK, INC.  
PITTSBURGH, PA 15239.  
INFO@UNIPACKING.COM  
MADE IN USA

Questions or Comments: 724-733-7381

## PRINCIPAL DISPLAY PANEL - 57 g Carton Label

Avedana<sup>®</sup>  
HEMORRHOIDAL PAIN RELIEF OINTMENT

Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

1 TUBE | NET WT 2 OZ (57 g)



## AVEDANA HEMORRHOIDAL PAIN RELIEF

mineral oil, petrolatum, phenylephrine hcl ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43749-480
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<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>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>THYME</b> (UNII: CW657OBU4N)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

### Product Characteristics

<b>Color</b>	yellow (smooth yellow ointment)	<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:43749-480-02	1 in 1 CARTON	01/06/2021	
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	03/01/2004	

**Labeler** - Unipack LLC (009248480)

## Establishment

Name	Address	ID/FEI	Business Operations
Unipack LLC		009248480	manufacture(43749-480)

Revised: 1/2023

Unipack LLC