

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

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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<br>in 1 g |
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)   | PETROLATUM  | 749 mg<br>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: CW6570BU4N)                    |          |
| <b>WHITE WAX</b> (UNII: 7G1J5DA97F)                |          |
| <b>TOCOPHEROL</b> (UNII: ROZB2556P8)               |          |

### 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 Drug | M015                                     | 03/01/2004           |                    |

**Labeler** - Unipack LLC (009248480)

**Registrant** - Unipack LLC (009248480)

## Establishment

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

Revised: 11/2024

Unipack LLC