

**AVEDANA HEMORRHOIDAL COOLING GEL- phenylephrine hcl, witch hazel gel**  
**Unipack LLC**

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**Avedana<sup>®</sup> Hemorrhoidal Cooling Gel**

**(Phenylephrine HCl, Witch Hazel)**

**Drug Facts**

***ACTIVE INGREDIENTS***

Phenylephrine HCl 0.25%

Witch hazel 50.0%

***PURPOSES***

Vasoconstrictor

Astringent

***USES***

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas

***WARNINGS***

**For external 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
- do not put this product into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

- bleeding occurs
- condition worsens or does not improve within 7 days

**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 gel.
- when first opening the tube, puncture foil seal with top end of cap
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- children under 12 years of age: ask a doctor

***OTHER INFORMATION***

store at 15°C - 30°C (59°F - 89°F)

***INACTIVE INGREDIENTS***

aloe barbadensis leaf juice, edetate disodium, hydroxyethyl cellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, sulisobenzone, vitamin E

***QUESTIONS OR COMMENTS?***

Call weekdays 8 AM to 5 PM EST at **1-724-733-7381**

**PRINCIPAL DISPLAY PANEL - TUBE LABEL**

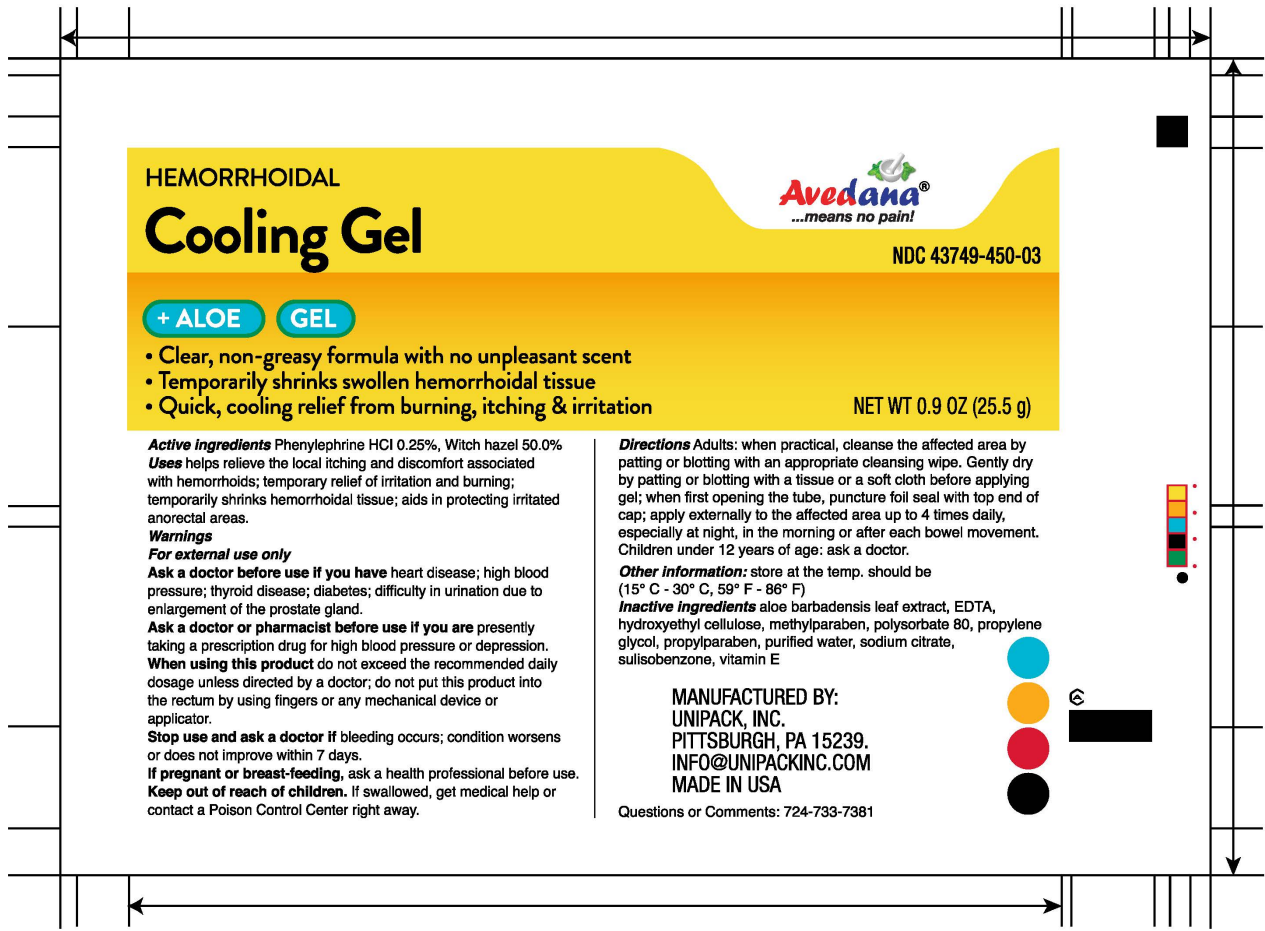
**Avedana®**

**HEMORRHOIDAL COOLING GEL**

Fast Cooling  
Relief

•Clear, Non-Greasy Formula with  
No Unpleasant Scent•Prompt, Cooling Relief from Painful  
Burning & Itching•Shrinks Swollen Hemorrhoidal Tissue•Relieves External Discomfort

1 TUBE | 25.5 g | THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER  
CARTON IS MISSING.



**PRINCIPAL DISPLAY PANEL - CARTON LABEL**

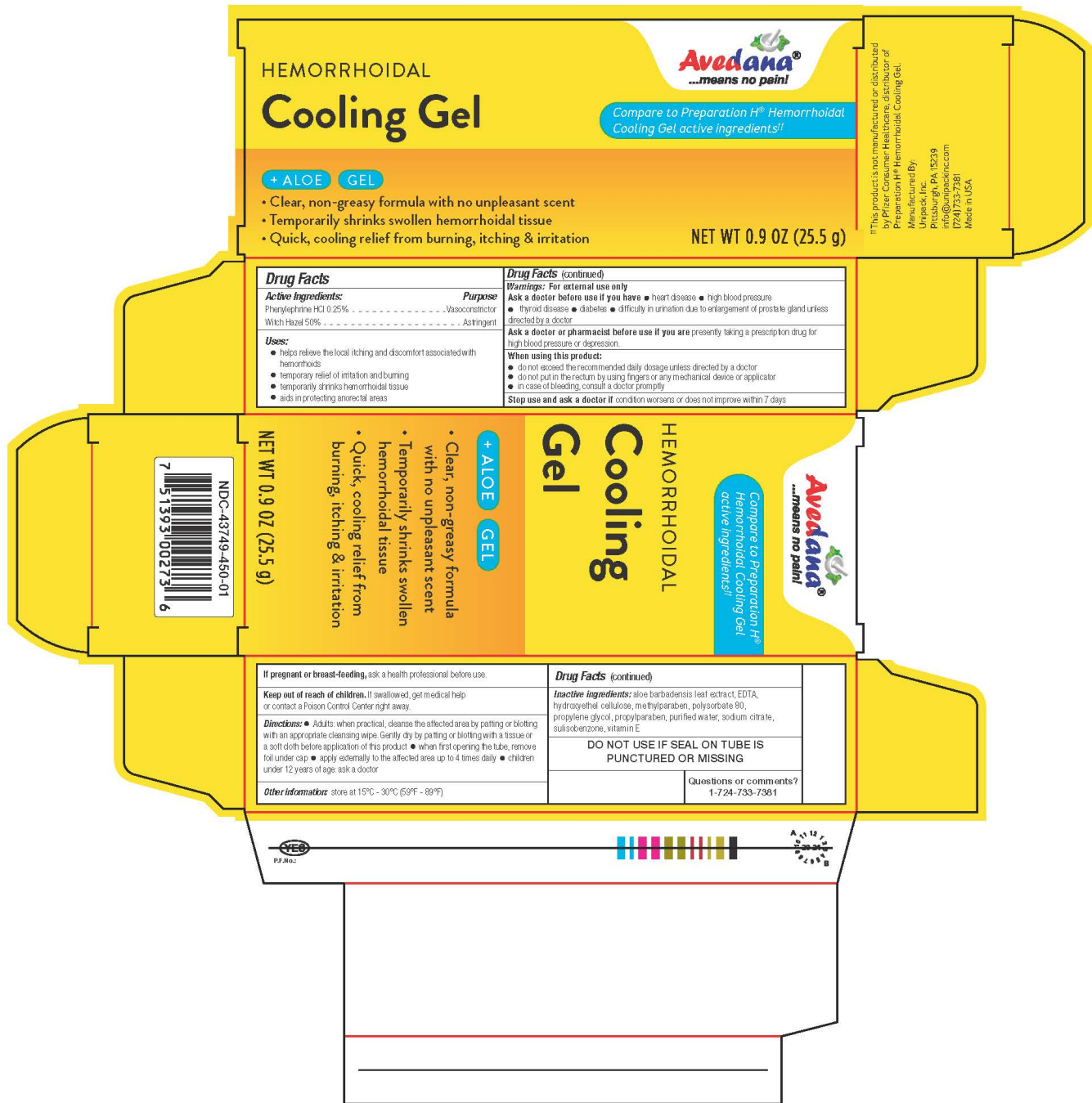
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- Clear, Non-Greasy Formula with No Unpleasant Scent
- Prompt, Cooling Relief from Painful Burning & Itching
- Shrinks Swollen Hemorrhoidal Tissue
- Relieves External Discomfort

1 TUBE INSIDE CARTON | NET WT 0.9 OZ (25.5 g)



## AVEDANA HEMORRHOIDAL COOLING GEL

phenylephrine hcl, witch hazel gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:43749-450 |
| <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>WITCH HAZEL</b> (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34)                    | WTCH HAZEL                  | 500 mg in 1 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                           |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)                         |          |
| <b>HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%)</b> (UNII: 8136Y38GY5) |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                            |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                           |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                         |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                            |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                    |          |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)         |          |
| <b>SULISOBENZONE</b> (UNII: 1W6L629B4K)                            |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)               |          |

### Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:43749-450-01 | 1 in 1 CARTON                                       | 01/01/2004           |                    |
| 1 |                  | 25.5 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                                     | 01/01/2004           |                    |

**Labeler** - Unipack LLC (009248480)

### Establishment

| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Unipack LLC |         | 009248480 | manufacture(43749-450) |

Revised: 2/2024

Unipack LLC