

**AVEDANA HEMORRHOIDAL MAXIMUM STRENGTH- hemorrhoidal cream  
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.*

-----  
**Avedana® Hemorrhoidal Pain Relief Cream**

**Active Ingredients**

Glycerin 14.4%

Phenylephrine HCL 0.25%

Pramoxine HCl 1%

White petrolatum 15%

**Purpose**

Protectant

Vasoconstrictor

Local anesthetic

Protectant

**Uses**

-for temporary relief of pain, soreness, and burning.

-helps relieve the local itching and discomfort associated with hemorrhoids.

-temporarily shrinks hemorrhoidal tissue.

-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
- 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 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
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling pain, or other symptoms develop or increase

**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 cream. When first opening the tube, puncture foil seal with top end of cap. Apply externally or in the lower portion of the anal canal only. Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.
- For application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover.
- children under 12 years of age: ask a doctor.

## **Directions**

Apply externally or in the lower portion of the anal canal only. Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.

-For application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.

## **Other information**

store at 15°C - 30°C (59°F - 86°F)

## **Inactive ingredients**

Aloe barbadensis leaf extract, butylated hydroxytoluene, cetyl esters, cetyl palmitate, glyceryl monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, sodium citrate, stearic acid, stearyl alcohol, vitamin E, water

## **Avedana Hemorrhoidal Cream<sup>®</sup> Maximum Strength w/ Aloe & Vitamin E Tube Label**

Tube Label 0.9oz

HEMORRHOIDAL

# Pain Relief Cream



NDC 43749-470-03

**MAXIMUM STRENGTH**

**+ ALOE & VITAMIN E**

**CREAM**

- Rapid, soothing relief from painful burning, itching & discomfort
- Shrinks swollen hemorrhoidal tissue
- Protects irritated tissue

NET WT 0.9 OZ (25.5 g)

**Active ingredients** Glycerin 14.4%; Phenylephrine HCl 0.25%; Pramoxine HCl 1%; White Petrolatum 15%

**Uses** for temporary relief of pain, soreness and burning; helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue; 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; 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; an allergic reaction develops; the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

**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 cream; when first opening the tube, puncture foil seal with top end of cap; apply externally or in the lower portion of the anal canal only. Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. For application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus. Thoroughly cleanse dispensing cap after each use and replace cover. Children under 12 years of age: ask a doctor.

**Other information:** store at 20-25°C (68-77°F)

**Inactive ingredients** aloe barbadensis leaf extract, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters, cetyl palmitate, glyceryl monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, stearic acid, tocopherol acetate

MANUFACTURED BY:

UNIPACK, INC.

PITTSBURGH, PA 15239.

**100% SATISFACTION GUARANTEED**

Made in USA

## Avedana Hemorrhoidal Cream<sup>®</sup> Maximum Strength w/ Aloe & Vitamin E 1 TUBE | NET WT 0.9 OZ (26 g)

0.9oz Carton Label

HEMORRHOIDAL



# Pain Relief Cream

Compare to Preparation H® Cream active ingredients!

**MAXIMUM STRENGTH + ALOE & VITAMIN E CREAM**

- Rapid, soothing relief from painful burning, itching & discomfort
- Shrinks swollen hemorrhoidal tissue
- Protects irritated tissue

NET WT 0.9 OZ (25.5 g)

If this product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Preparation H® Cream, Manufactured By: Unipac, Inc. Pittsburgh, PA 15239 [info@unipacinc.com](mailto:info@unipacinc.com) 1724-733-7381 Made in USA

### Drug Facts

#### Active Ingredients

Glycinn 14.4%	Protectant
Phenylephrine HCl 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local Anesthetic
White petrolatum 15%	Protectant

**Uses:**

- for temporary relief for pain, soreness and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

### Drug Facts (continued)

#### 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 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 in the rectum by using fingers or any mechanical device or applicator

**Stop use and ask doctor if:**

- bleeding occurs
- condition worsens or does not improve within 7 days
- an allergic reaction occurs
- the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase



NET WT 0.9 OZ (25.5 g)

- Rapid, soothing relief from painful burning, itching & discomfort
- Shrinks swollen hemorrhoidal tissue
- Protects irritated tissue

**MAXIMUM STRENGTH + ALOE & VITAMIN E CREAM**

# Pain Relief Cream



Compare to Preparation H® Cream active ingredients!

### Drug Facts (continued)

**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 cream
- when first opening the tube, puncture foil seal with top end of cap
- apply externally or in the lower portion of the anal canal only
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. For application in the lower anal canal: remove cover from dispensing cap
- Attach dispensing cap to tube
- Lubricate dispensing cap well.

### Drug Facts (continued)

Then gently insert dispensing cap partway into the anus.

- Thoroughly cleanse dispensing cap after each use and replace cover
- children under 12 years of age ask a doctor

**Other information:** store at 15°C - 30°C (59°F - 86°F)

**Inactive ingredients:** aloe barbadensis leaf extract, butylated hydroxytoluene, octostearyl alcohol, cetyl esters, cetyl palmitate, glyceryl monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polyisobutene 60, propylene glycol, propylparaben, purified water, sodium citrate, stearic acid, tocopherol acetate.

Questions or comments? 1-724-733-7381



## Avedana Hemorrhoidal Cream®

### Maximum Strength w/ Aloe & Vitamin E

### 1 TUBE | NET WT 1.8 OZ (51 g)

1.8oz Tube Label

HEMORRHOIDAL

# Pain Relief Cream



NDC 43749-470-04

MAXIMUM STRENGTH

+ ALOE & VITAMIN E

CREAM

- Rapid, soothing relief from painful burning, itching & discomfort
- Shrinks swollen hemorrhoidal tissue
- Protects irritated tissue

NET WT 1.8 OZ (51 g)

**Active ingredients** Glycerin 14.4%; Phenylephrine HCl 0.25%; Pramoxine HCl 1%;  
White Petrolatum 15%

**Uses** for temporary relief of pain, soreness and burning; helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue; 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; 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; an allergic reaction develops; the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

**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 cream; when first opening the tube, puncture foil seal with top end of cap; apply externally or in the lower portion of the anal canal only. Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. For application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus. Thoroughly cleanse dispensing cap after each use and replace cover. Children under 12 years of age: ask a doctor.

**Other information:** store at 20-25°C (68-77°F)

**Inactive ingredients** aloe barbadensis leaf extract, butylated hydroxytoluene, cetostearyl alcohol, cetyl esters, cetyl palmitate, glyceryl monostearate, isopropyl myristate, lanolin, methylparaben, mineral oil, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, stearic acid, tocopherol acetate

MANUFACTURED BY:  
UNIPACK, INC.  
PITTSBURGH, PA 15239.  
100% SATISFACTION GUARANTEED

## Avedana Hemorrhoidal Cream<sup>®</sup> Maximum Strength w/ Aloe & Vitamin E 1 TUBE | NET WT 1.8 OZ (51 g)

1.8oz Carton Label



## AVEDANA HEMORRHOIDAL MAXIMUM STRENGTH

hemorrhoidal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43749-470
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
<b>GLYCERIN</b> (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE -	PRAMOXINE	10 mg

UNII:068X84E056)	HYDROCHLORIDE	in 1 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	25 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>ALOE</b> (UNII: V5VD430YW9)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

### Product Characteristics

<b>Color</b>	white	<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:43749-470-01	1 in 1 CARTON	11/04/2020	
1	NDC:43749-470-03	25.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43749-470-02	1 in 1 CARTON	11/04/2020	
2	NDC:43749-470-04	51 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	11/04/2020	

**Labeler** - Unipack LLC (009248480)



**Registrant** - Unipack LLC (009248480)

**Establishment**

Name	Address	ID/FEI	Business Operations
Unipack LLC		009248480	manufacture(43749-470)

Revised: 1/2023

Unipack LLC