

**AVEDANA HEMORRHOIDAL MAXIMUM STRENGTH- hemorrhoidal cream
Unipack LLC**

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.

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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 [®] 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		
<ul style="list-style-type: none">• Rapid, soothing relief from painful burning, itching & discomfort• Shrinks swollen hemorrhoidal tissue• Protects irritated tissue		NET WT 0.9 OZ (25.5 g)
<p>Active ingredients Glycerin 14.4%; Phenylephrine HCl 0.25%; Pramoxine HCl 1%; White Petrolatum 15%</p> <p>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</p> <p>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.</p>		<p>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.</p> <p>Other information: store at 20-25°C (68-77°F)</p> <p>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</p> <p>MANUFACTURED BY: UNIPACK, INC. PITTSBURGH, PA 15239. 100% SATISFACTION GUARANTEED Made in USA</p>

Avedana Hemorrhoidal Cream[®]
Maximum Strength w/ Aloe & Vitamin E
1 TUBE | NET WT 0.9 OZ (26 g)

0.9oz Carton Label



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)

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White Petrolatum 15%

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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[®] 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

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

Active Ingredient/Active Moiety

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

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

Inactive Ingredients

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

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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 Drug	M015	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: 11/2024

Unipack LLC