

**AVEDANA HEMORRHOIDAL- hemorrhoidal rectal suppositories suppository
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 ® 24 ct Hemorrhoidal Rectal Suppository

Drug Facts

Active Ingredients	Purpose
Cocoa butter 88.44%.....	Protectant
Phenylephrine hydrochloride 0.25%.....	Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily relieves burning and 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 rectal use only

Ask a doctor or pharmacist before use if you are

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression

Ask a doctor before use if you have

- Ask a doctor before use if you have
- heart disease -high blood pressure
- t hyroid disease -diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

When using this product do not exceed the recommended daily dosage unless directed by a doctor

Stop use and ask a doctor

Stop use and ask a doctor if bleeding occurs or if condition worsens or does not improve within 7 days

If pregnant or breastfeeding

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Adults

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-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 insertion of this product.

-detach one suppository from the strip; remove the foil wrapper before inserting into the rectum as follows:

-hold suppository with rounded end up

-as shown, carefully separate foil tabs by inserting tip of fingernail at end marked "peel down"

-slowly and evenly peel apart (do not tear) foil by pulling tabs down both sides, to expose from wrapper

-insert one suppository into the rectum 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

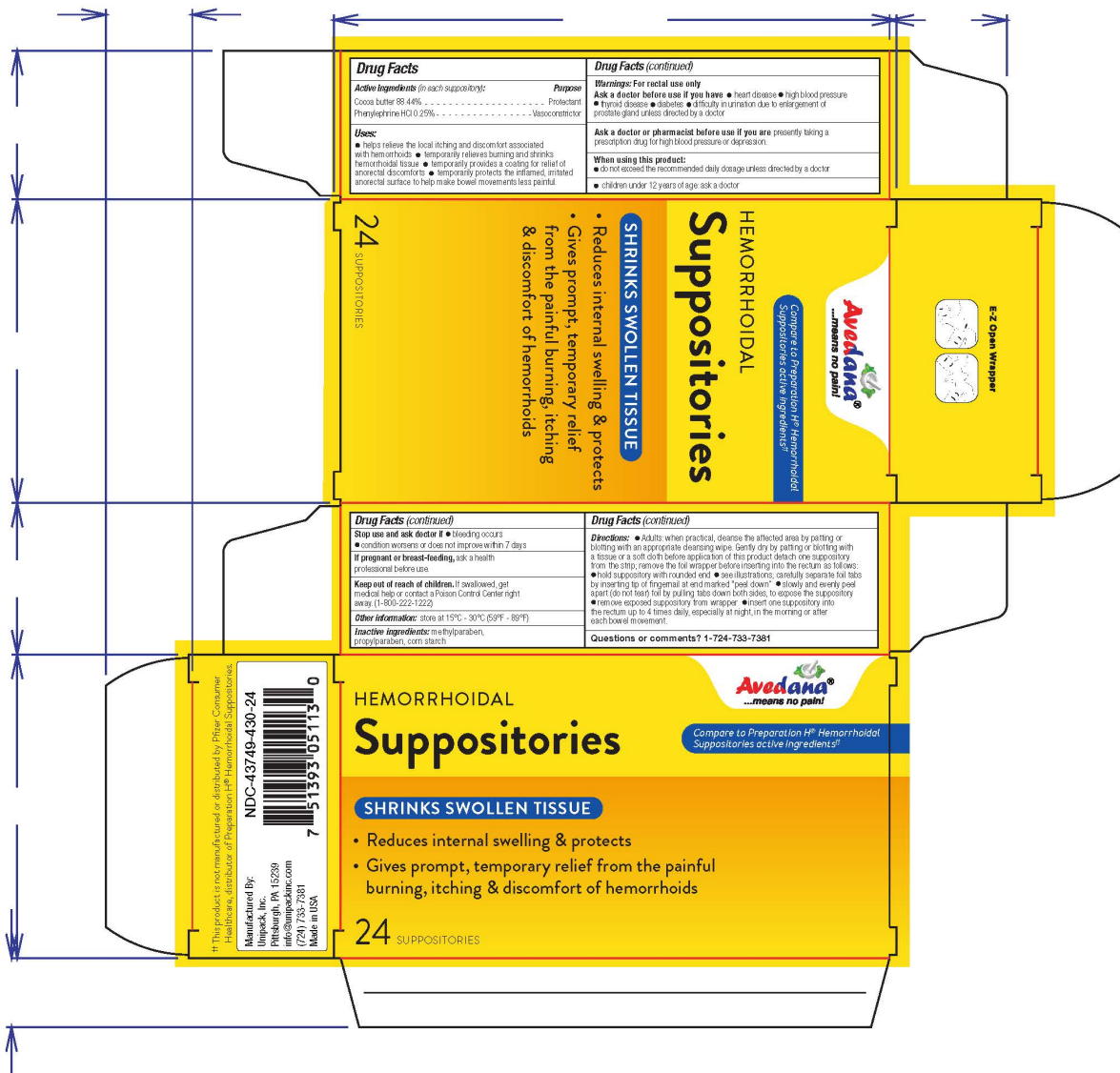
Other information

Store at 20°C-25°C (68°F-77°F)

Inactive ingredients

corn starch, methylparaben, propylparaben

Carton



AVEDANA HEMORRHOIDAL

hemorrhoidal rectal suppositories suppository

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:43749-430

Route of Administration	RECTAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	2211 mg	
	PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	6.25 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	METHYLPARABEN (UNII: A2I8C7HI9T)			
	PROPYLPARABEN (UNII: Z8IX2SC1OH)			
	MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)			
Product Characteristics				
Color	white	Score		
Shape	BULLET	Size	32mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-430-24	4 in 1 CARTON	10/26/2020	
1	NDC:43749-430-25	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M015	10/26/2020		

Labeler - Unipack LLC (009248480)

Registrant - Unipack LLC (009248480)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack LLC		009248480	manufacture(43749-430)

