

## **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 ® 12 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  
-thyroid 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

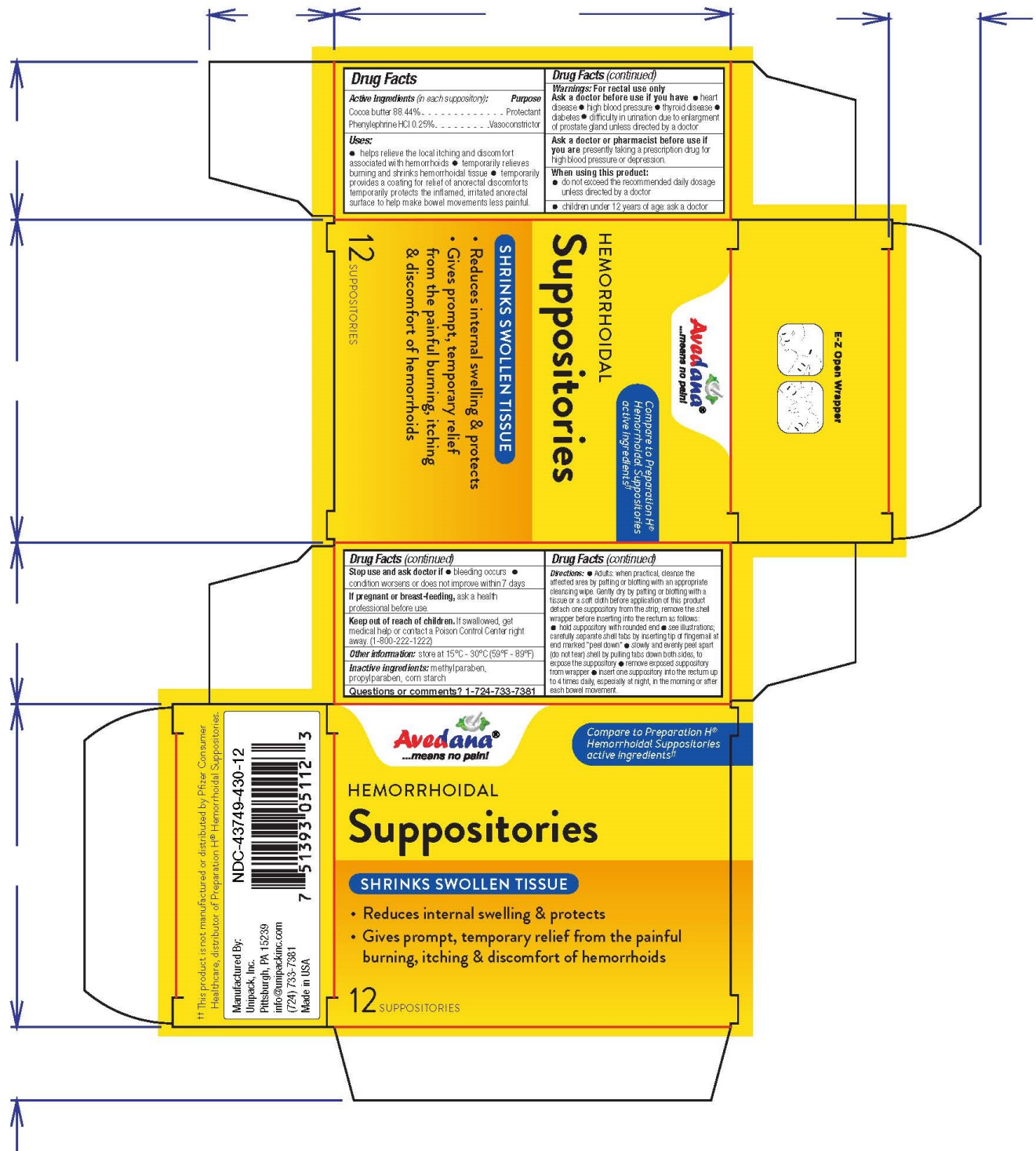
**Other information**

Store at 20oC-25oC (68oF-77oF)

**Inactive ingredients**

corn starch, methylparaben, propylparaben

**Label**



## 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
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	2211 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	6.25 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE)</b> (UNII: 461P5CJN6T)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	BULLET	<b>Size</b>	32mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-430-12	2 in 1 CARTON	09/17/2017	
1	NDC:43749-430-13	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	09/18/2014	

**Labeler** - Unipack LLC (009248480)**Registrant** - Unipack LLC (009248480)**Establishment**

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