

## **HEMORRHOIDAL RELIEF- cocoa butter, phenylephrine hcl suppository**

### **Rite Aid Corporation**

*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.*

-----

### **Rite Aid Corporation Hemorrhoidal Relief Suppositories Drug Facts**

#### **Active ingredients (in each suppository)**

Cocoa butter 88.44%

Phenylephrine HCl 0.25%

#### **Purposes**

Protectant

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 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

#### **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. (1-800-222-1222)

**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 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
- see illustrations: 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 the suppository
- remove exposed suppository 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 20-25°C (68-77°F)

**Inactive ingredients**

methylparaben, propylparaben, topical starch

**Questions or comments?**

1-800-719-9260

**Package/Label Principal Display Panel**

Compare to the active ingredients of Preparation H® Hemorrhoidal Suppositories

hemorrhoidal relief suppositories

cocoa butter 88.44%

phenylephrine HCl 0.25%

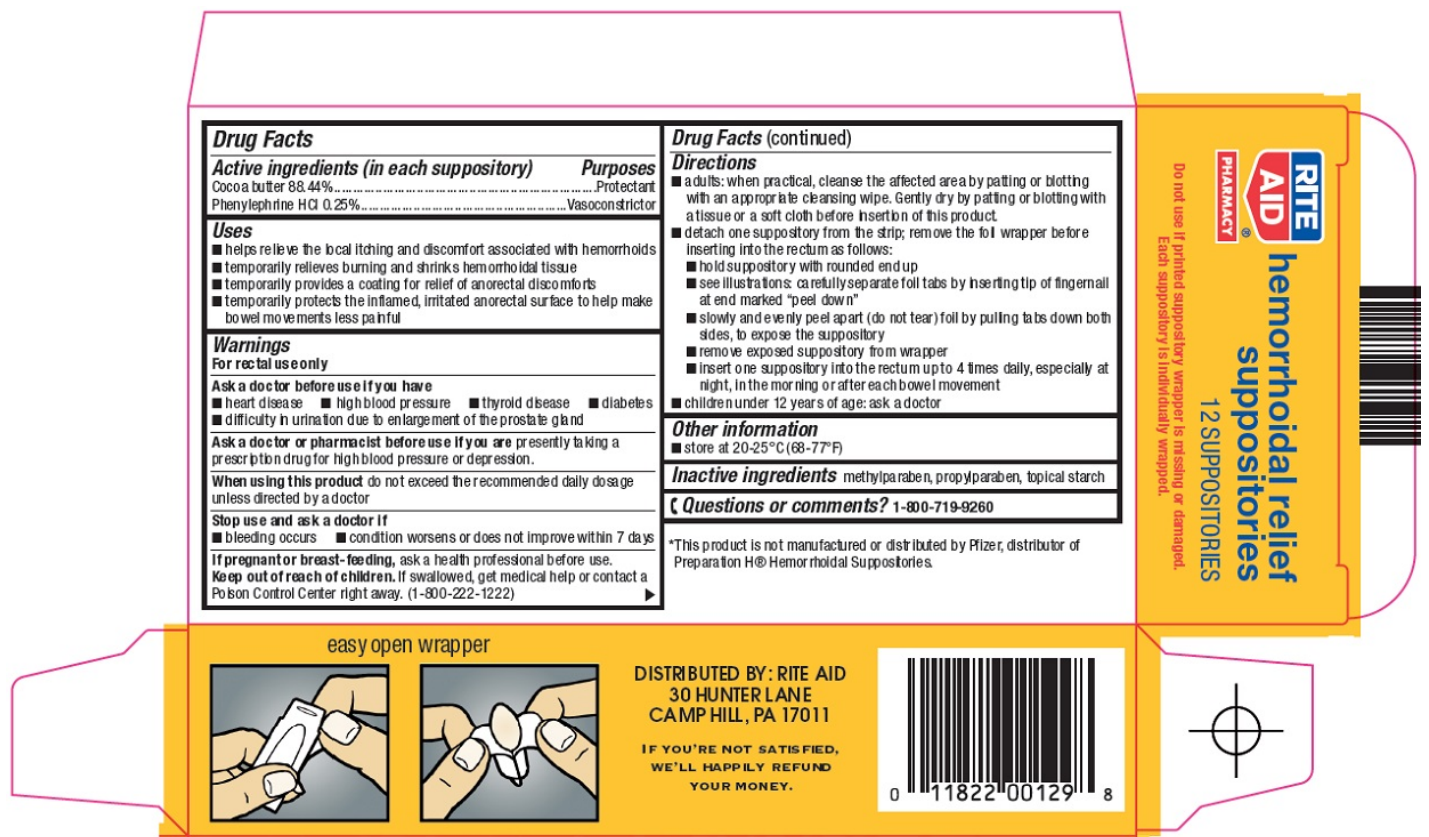
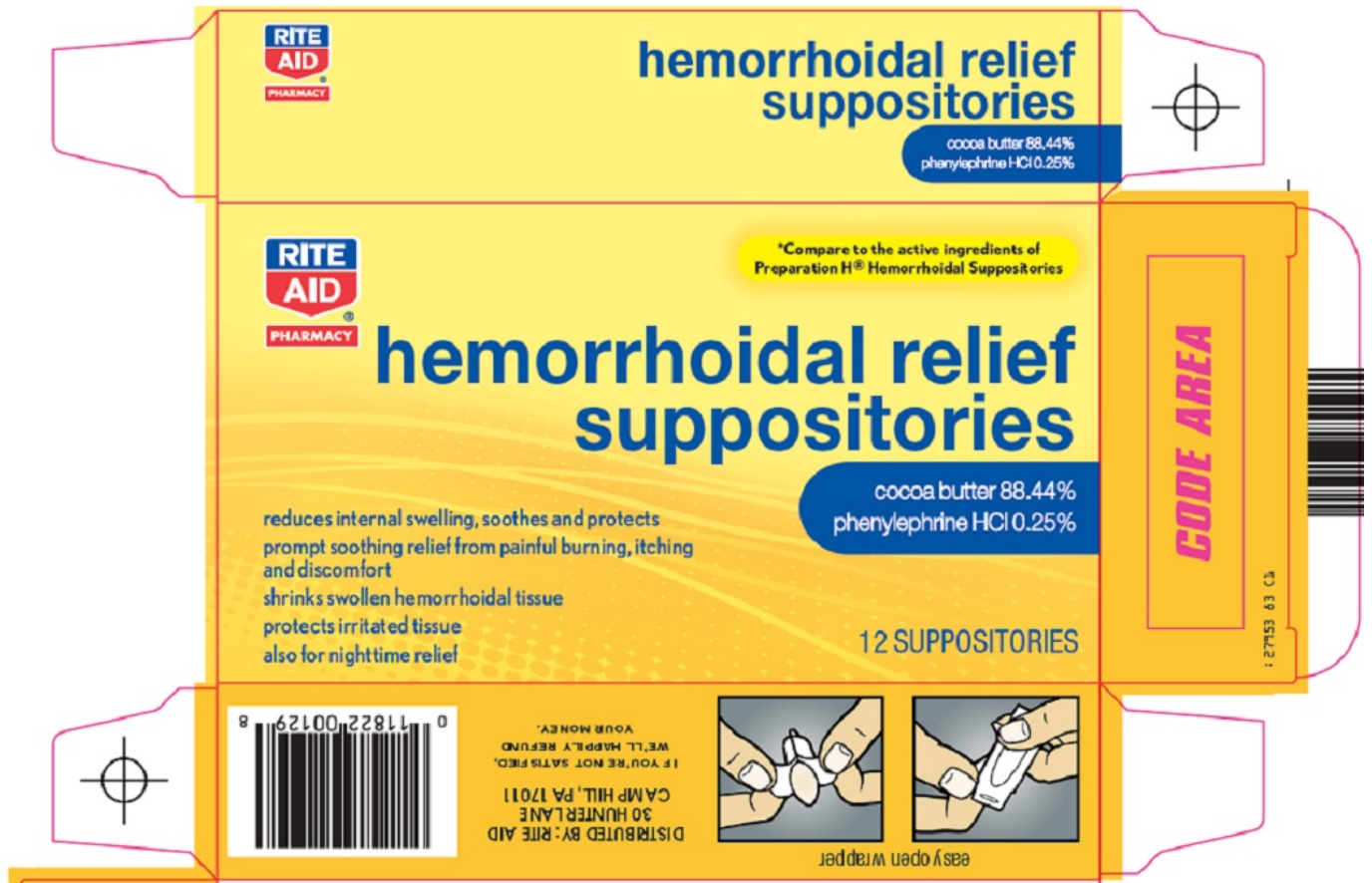
reduces internal swelling, soothes and protects

prompt soothing relief from painful burning, itching and discomfort

shrinks swollen hemorrhoidal tissue

protects irritated tissue

also for nighttime relief



cocoa butter, phenylephrine hcl suppository

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0005
<b>Route of Administration</b>	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	6.5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>METHYL PARABEN</b> (UNII: A218C7H9T)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	YELLOW (light)	<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:11822-0005-1	12 in 1 CARTON	01/09/2015	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-0005-2	24 in 1 CARTON	01/09/2015	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11822-0005-3	48 in 1 CARTON	01/09/2015	
3		1 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	part346	01/09/2015	

**Labeler** - Rite Aid Corporation (014578892)