

**PREMIER VALUE HEMORRHOIDAL- hemorrhoidal rectal suppositories suppository**  
**Chain Drug Consortium**

*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.*

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**Drug Facts**

Active Ingredients	Purpose
(per suppository)	
Cocoa butter 88.44%.....	Protectant
Phenylephrine hydrochloride 0.25%.....	Vasoconstrictor

**Uses**

- temporarily shrinks hemorrhoidal tissues
- gives temporary relief to the itching, burning, and discomfort associated with hemorrhoids
- aids in protecting irritated anorectal areas

**Warnings**

For rectal use only

**Directions**

**Adults**

- detach one suppository from the strip. Remove the wrapper before inserting into the rectum
- 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: consult a doctor

**Other information**

Store at room temperature or in a cool place but not over 80°F

**Inactive ingredients**

methylparaben, propylparaben, starch

**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**

- 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

-in case of bleeding or if condition worsens or does not improve within 7 days, consult a doctor promptly

**If pregnant or breast-feeding,**

If pregnant or breast-feeding, 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

**Product Label**



## PREMIER VALUE HEMORRHOIDAL

hemorrhoidal rectal suppositories suppository

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-321
Route of Administration	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	88.44 g in 100 g

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)

PHENYLEPHRINE  
HYDROCHLORIDE

.25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
METHYL PARABEN (UNII: A2I8C7HI9T)	.02 g in 100 g
PROPYL PARABEN (UNII: Z8IX2SC1OH)	.02 g in 100 g
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	11.27 g in 100 g

### 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:68016-321-13	2 in 1 CARTON		
1	NDC:68016-321-12	12 g in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/25/2015	

**Labeler** - Chain Drug Consortium (101668460)

### Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(68016-321)

Revised: 3/2015

Chain Drug Consortium