# 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  $80^{\text{lo}} \text{ IF}$ 

# **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

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- -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**



# Hemorrhoidal Suppositories



NDC: 68016-321-12 COMPARE TO PREPARATION H® SUPPOSITORIES ACTIVE INGREDIENTS\*



DISTRIBUTED BY CHAIN DRUG CONSORTIUM 3301 NW BOCA RATON BLVD SUITE 101, BOCA RATON, FL 33431 MADE IN USA

Hemorrhoidal Suppositories

HELPS REDUCE INFLAMMATION AND SWELLING OF HEMORRHOIDAL TISSUES PROVIDES TEMPORARY RELIEF IN MANY CASES

#### 12 SUPPOSITORIES

TAMPER-EVIDENT: FOR YOUR SAFETY, SUPPOSITORIES ARE PACKED IN TAMPER-EVIDENT SEALED WRAPPER. DO NOT USE IF WRAPPER IS TORN OR OPEN.

\*This product is not manufactured or distributed by WHITEHALL LABORATORIES INC., owner of the registered trademark Preparation  $H \otimes$ 

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STRIP IN UPC:

# Hemorrhoidal Suppositories



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Inactive ingredients

**INK AND COATING FREE** 

# 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

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	Ingredient Name	Basis of Strength	Strength
	COCOA BUTTER (UNII: 5120YT1CRR) (COCOA BUTTER - UNII:5120YT1CRR)	COCOA BUTTER	88.44 g

Inactive Ingredients	
Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8 C7HI9 T)	.02 g in 100 g
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	.02 g in 100 g
MO DIFIED CORN STARCH (1-O CTENYL SUCCINIC ANHYDRIDE) (UNII: 46 1P5CJN6T)	11.27 g in 100 g

Product Characteristics			
Color	white	Score	
Shape	BULLET	Size	32mm
Flavor		Imprint Code	
Contains			

	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:68016-321-13	2 in 1 CARTON			
ı	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