

## **HEMORRHOIDAL- cocoa butter, phenylephrine hydrochloride suppository GRAXCELL PHARMACEUTICAL, 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.*

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### **HEMORRHOIDAL SUPPOSITORIES, 70795-1021**

#### **Active Ingredients (per suppository)**

Cocoa butter 88.44 %

Phenylephrine hydrochloride 0.25 %

#### **Purpose**

Protectant

Vasoconstructor

#### **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**

##### **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
- thyroid disease
- high blood pressure
- diabetes
- difficulty in urination due to enlargement of the prostate gland

##### **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**

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.

## Directions Adults

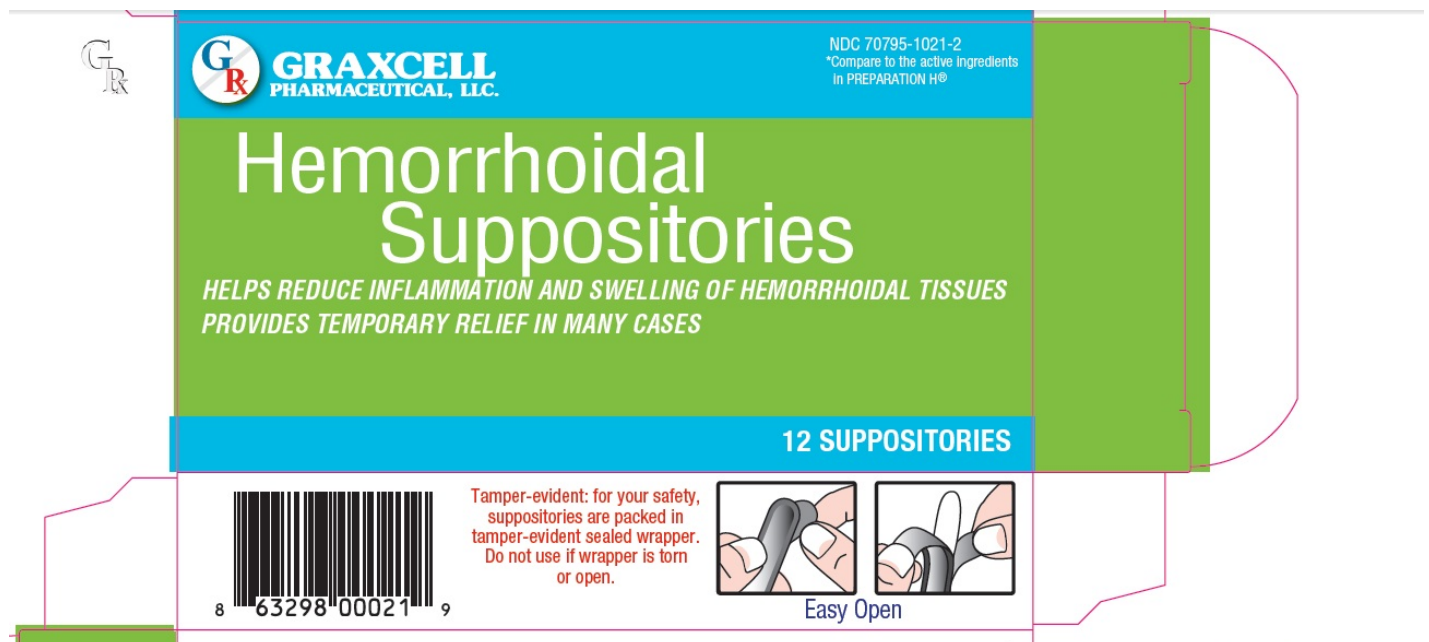
- detach one suppository from the strip. Remove the wrapper before inserting into the rectum.
- insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement. Children under 12 years of age: consult doctor

## Other Information

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

## Inactive ingredients

methylparaben, propylparaben, starch





**GRAXCELL**  
PHARMACEUTICAL, LLC.

NDC 70795-1021-4  
\*Compare to the active ingredients  
in PREPARATION H®

# Hemorrhoidal Suppositories

Reduces Internal Swelling | Soothes and Protects

Cocoa Butter 88.44% | Phenylephrine Hydrochloride 0.25%

Prompt Soothing Relief From Painful Burning, Itching and Discomfort  
Provides Additional Nighttime Relief

24 Suppositories

## HEMORRHOIDAL

cocoa butter, phenylephrine hydrochloride suppository

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70795-1021
<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	1768.8 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-1021-2	12 in 1 BOX	03/29/2017	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
	NDC:70795-			

2	NDC: 70795-1021-4	24 in 1 BOX	04/22/2017	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part346		03/29/2017	

**Labeler** - GRAXCELL PHARMACEUTICAL, LLC (056556923)

**Registrant** - GRAXCELL PHARMACEUTICAL, LLC. (056556923)

Revised: 12/2021

GRAXCELL PHARMACEUTICAL, LLC