

HEMORRHOIDAL- cocoa butter, phenylephrine hydrochloride suppository
GRAXCELL PHARMACEUTICAL, LLC

GRAXCELL PHARMACEUTICAL - 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

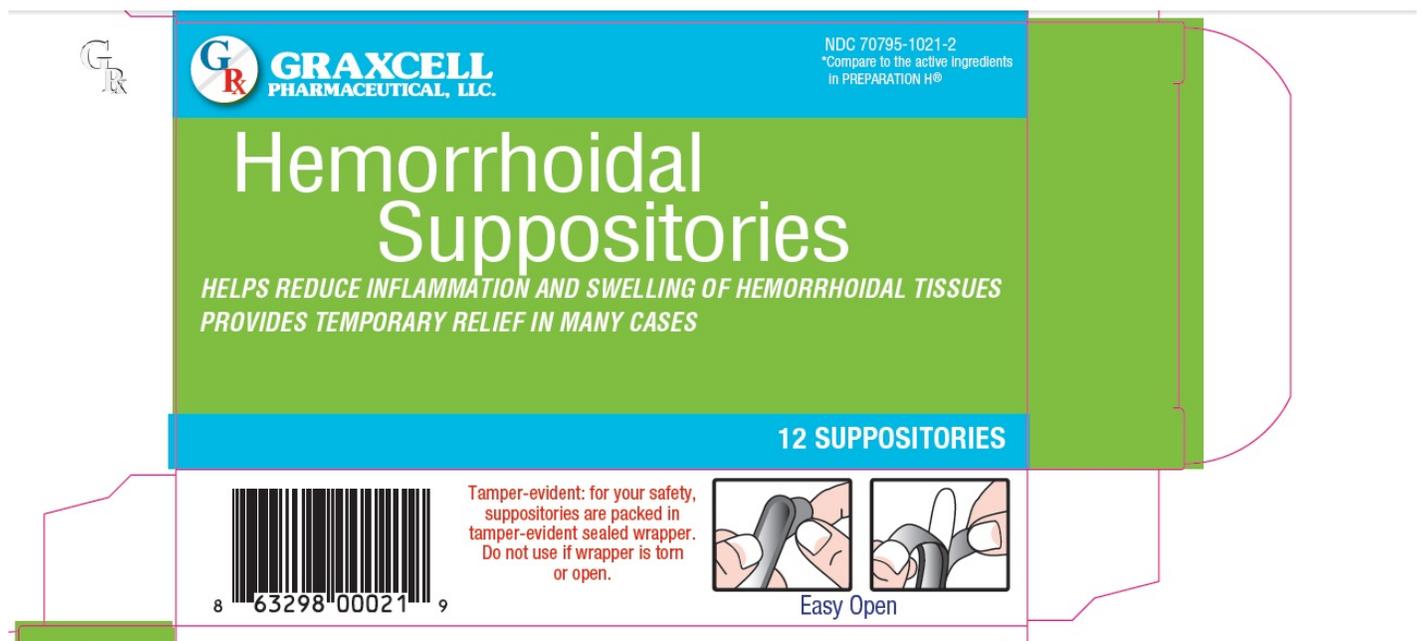
- detach one suppository from the strip. Remove the wrapper before inserting into the rectum.
- insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement. Children under 12 years of age: consult doctor

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70795-1021
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	1768.8 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STARCH, CORN (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		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015		03/29/2017	

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Registrant - GRAXCELL PHARMACEUTICAL, LLC. (056556923)

Establishment			
Name	Address	ID/FEI	Business Operations
Graxcell Pharmaceutical llc		056556923	manufacture(70795-1021)

Revised: 12/2025

GRAXCELL PHARMACEUTICAL, LLC