HEMORRHOIDAL- cocoa butter, phenylephrine hydrochloride suppository Chain Drug Marketing Association, Inc.

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.

Chain Drug Marketing Association - Hemorrhoidal Suppository

Active Ingredients

Active Ingredients (per suppository)

Cocoa butter 88.44 % Phenylephrine hydrochloride 0.25 %

Purposes

Protectant Vasoconstructor

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

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.

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



Hemorrhoidal Suppositories

Reduces Internal Swelling | Soothes and Protects

NDC 63868-208-12



*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

12 Adult Suppositories



Distributed by C.D.M.A., Inc.© 43157 W. Nine Mile Novi, MI 48376-0995 www.qualitychoice.com Questions: 248-449-9300





Easy Open

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*This product is not manufactured or distributed by Pfizer Consumer Healthcare., distributor of Preparation H°.

HEMORRHOIDAL

cocoa butter, phenylephrine hydrochloride suppository

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-208
Route of Administration	RECTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
COCOA BUTTER (UNII: 5120YT1CRR) (COCOA BUTTER - UNII:5120YT1CRR)	COCOA BUTTER	1768.8 mg	

PHENYLEPHRINE HYDROCHLORIDE

5 mg

Inactive Ingredients			
Ingredient Name Streng			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			
STARCH, CORN (UNII: 08232NY3SJ)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63868-208- 12	12 in 1 BOX	05/18/2021		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:63868-208- 24	24 in 1 BOX	05/18/2021		
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 final	part346	09/26/2007	

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Registrant - Acino Products, LLC. (019385518)

Establishment				
Name	Address	ID/FEI	Business Operations	
Acino Products, LLC.		019385518	manufacture(63868-208)	

Revised: 5/2021 Chain Drug Marketing Association, Inc.