CALMOL 4- zinc oxide and cocoa butter suppository Resical Inc.

Calmol 4 Suppositoires

Active Ingredients (in each suppository)

Cocoa Butter 76%

Zinc Oxide 10%

Purpose

Protectant

Astringent

Uses

- gives temporary relief of burning, irritation, itching and discomfort associated with hemorrhoids
- temporarily provides a coating for for anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For rectal use only

When using this product

do not exceed the recommended daily dosage unless directed by a doctor

Stop use and ask doctor if

bleeding occurs or if condition worsens or does not improve within 7 days

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: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing pad

- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- detach one suppository from the strip; remove wrapper before inserting into rectum as follows:
 - slowly peel down film wrapper by pulling evenly and slowly on tabs to expose suppository
- insert 1 suppository bulb shape first into the rectum up to 6 times daily or after each bowl movement
- children under 12 years of age, consult a doctor

Other information

- store in a cool place not ober 80°F to avoid melting
- if subjected to higher temperatures, refrigeration may restore to a usable condition

Inactive ingredients

Bismuth subgallate, glyceryl stearate, hydrogenated vegetable oil, methylparaben, propylparaben

Questions or comments?

Call toll-free **1-800-204-6434** weekdays 9 AM to 5 PM EST

Calmol 4 Suppository 24 count

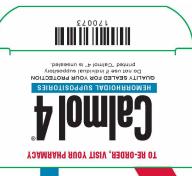
Calmol 4 Hemorrhoidal Suppository

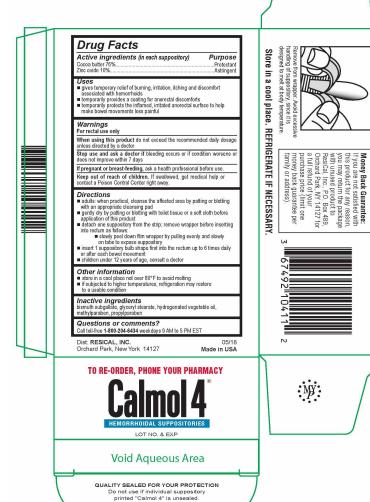
24 count

Distributed by: Resical Inc.

Orchard Park, New York 14127

The image below depicts a representative sample of packaging that is available.





HEMORRHOIDAL SUPPOSITORIES

& better Retention For easier Insertion

24 SUPPOSITORIES

Astringent & Protectant

Store in a cool place. REFRIGERATE IF NECESSARY Astringent & Protectant

Heart DiseaseHigh Blood PressureThyroid DiseaseDiabetes

Preferred Shape

SAFE AND
EFFECTIVE
TO Label Warnings For:

CALMOL 4

zinc oxide and cocoa butter suppository

Product Information HUMAN OTC DRUG Item Code (Source) NDC:67492-104 **Product Type RECTAL Route of Administration**

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	270 mg	
COCOA BUTTER (UNII: 5120YT1CRR) (COCOA BUTTER - UNII:5120YT1CRR)	COCOA BUTTER	2052 mg	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
FAT, HARD (UNII: 8334LX7S21)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
BISMUTH SUBGALLATE (UNII: YIW503MI7V)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67492-104- 11	4 in 1 CARTON	05/13/2006	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:67492-104- 12	2 in 1 CARTON	05/13/2006	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:67492-104- 13	1 in 1 CARTON	05/13/2006	
3		2 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	05/13/2006	

Labeler - Resical Inc. (927081369)

Registrant - DSC Laboratories Inc. (097807374)

Establishment				
Name	Address	ID/FEI	Business Operations	
DSC Laboratories Inc.		097807374	manufacture(67492-104)	

Revised: 12/2023 Resical Inc.