HEMORRHOIDAL- cocoa butter, phenylephrine hcl suppository Kroger Company

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.

Kroger Co. Hemorrhoidal Suppositories Drug Facts

Active ingredients (in each suppository)

Cocoa butter 88.44% Phenylephrine HCl 0.25%

Purposes

Protectant

Vasoconstrictor

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily relieves burning and shrinks hemorrhoidal tissue
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For rectal use only

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug for high blood pressure or depression.

When using this product

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

Stop use and ask a doctor if

- bleeding occurs
- 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. (1-800-222-1222)

Directions

- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before insertion of this product.
- detach one suppository from the strip; remove the foil wrapper before inserting into the rectum as follows:
- hold suppository with rounded end up
- see illustrations: carefully separate foil tabs by inserting tip of fingernail at end marked "peel down"
- slowly and evenly peel apart (do not tear) foil by pulling tabs down both sides, to expose the suppository
- remove exposed suppository from wrapper
- 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: ask a doctor

Other information

• store at 20-25°C (68-77°F)

Inactive ingredients

methylparaben, propylparaben, topical starch

Questions or comments?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO the active ingredients of PREPARATION H[®] HEMORRHOIDAL SUPPOSITORIES See back panel OUR PHARMACIST RECOMMENDED Hemorrhoidal Suppositories Reduces Internal Swelling Prompt Soothing Relief from Painful Burning, Itching & Discomfort Shrinks Swollen Hemorrhoidal Tissue Protects Irritated Tissue Also for Nighttime Relief



HEMORRHOIDAL cocoa butter, phenylephrine hcl suppository							
Product Information							
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-279				
Route of Administration	RECTAL						

Active Ingredient/Active Moiety								
Ingredient Name			Basis of Strength		Strength			
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII: 512OYT1CRR)			COCOA BUTTER		2211 mg			
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE UNII:1WS297W6MV)		Ε-	PHENYLEPHRINE HYDROCHLORIDE		6.5 mg			
Inactive Ingredients								
Ingredient Name					th			
METHYLPARABEN (UNII: A2I8C7HI9T)								
PROPYLPARABEN (UNII: Z8IX2SC1OH)								
STARCH, CORN (UNII: 08232NY3SJ)								
Product Characteristics								
		Score	Score					
Shape								
Flavor Imprint Code		Code						
Contains		•						
Packaging								
# Item Code	Package Description	Mark	eting Start Date	e Marketing	End Date			
NDC:30142-279-62 24 in 1 CARTON		08/23/	2014					
1 1 in 1 BLISTER PACK; Type 0: Not a Combination Product								
Marketing Information								
Marketing Category Application Number or Monograph Citation		Mark	larketing Start Date Marketing		End Date			
DTC monograph final part346		08/23/2	8/23/2014					

Labeler - Kroger Company (006999528)

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Kroger Company