

CAREONE HEMORRHOIDAL- cocoa butter and phenylephrine hydrochloride suppository
American Sales 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.

American Sales Company Hemorrhoidal Suppositories Drug Facts

Active ingredients (in each suppository)

Cocoa butter 85.39%

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

corn starch, methylparaben, propylparaben, shark liver oil

Package/Label Principal Display Panel

Compare to the Active Ingredients in Preparation H®

E-Z OPEN WRAPPER

HEMORRHOIDAL SUPPOSITORIES

Reduces internal swelling. Soothes and protects.

Prompt soothing relief from painful burning, itching and discomfort

Shrinks swollen hemorrhoidal tissue

Also for nighttime relief

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 WRAPPER

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12
 SUPPOSITORIES

CODE AREA



CE 145017

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Drug Facts (continued)

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

Do not use if printed suppository wrapper is missing or damaged.
 Each suppository is individually wrapped.



CAREONE HEMORRHOIDAL

cocoa butter, phenylephrine hcl suppository

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41520-160
Route of Administration	RECTAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (COCOA BUTTER)	COCOA BUTTER	2.135 g in 2.5 g
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	.0065 g in 2.5 g

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN	
METHYLPARABEN	
PROPYLPARABEN	
SHARK LIVER OIL	

Product Characteristics

Color	YELLOW	Score	
Shape	BULLET	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-160-53	2 in 1 CARTON		
1		15 g in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/02/2013	

Labeler - American Sales Company (809183973)

Revised: 3/2013

American Sales Company