

CAREONE HEMORRHOIDAL- cocoa butter, phenylephrine hcl 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 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?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredients in Preparation H® Hemorrhoidal Suppositories

HEMORRHOIDAL SUPPOSITORIES

Cocoa Butter – Phenylephrine HCl

Reduces internal swelling.

Soothes and protects.

Prompt soothing relief from painful burning, itching and discomfort

Shrinks swollen hemorrhoidal tissue

Actual Size

Protects irritated tissue

Also for nighttime relief

OUR PHARMACISTS RECOMMEND

12 SUPPOSITORIES

Easy open wrapper

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



CAREone®

NDC 41520-004-53

Compare to the active ingredients in Preparation H® Hemorrhoidal Suppositories**

HEMORRHOIDAL SUPPOSITORIES


Cocoa Butter • Phenylephrine HCl

Reduces internal swelling. Soothes and protects.
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Actual Size



12 SUPPOSITORIES



<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients (in each suppository)</th><th>Purposes</th></tr></thead><tbody><tr><td>Cocoa butter 88.44%</td><td>Protectant</td></tr><tr><td>Phenylephrine HCl 0.25%</td><td>Vasoconstrictor</td></tr></tbody></table> <p>Uses</p> <ul style="list-style-type: none">helps relieve the local itching and discomfort associated with hemorrhoidstemporarily relieves burning and shrinks hemorrhoidal tissuetemporarily provides a coating for relief of anorectal discomfortstemporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful <p>Warnings For rectal use only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">heart diseasehigh blood pressurethyroid diseasediabetesdifficulty in urination due to enlargement of the prostate gland <p>Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.</p> <p>When using this product do not exceed the recommended daily dosage unless directed by a doctor</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none">bleeding occurscondition worsens or does not improve within 7 days <p>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)</p>	Active ingredients (in each suppository)	Purposes	Cocoa butter 88.44%	Protectant	Phenylephrine HCl 0.25%	Vasoconstrictor	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none">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:<ul style="list-style-type: none">hold suppository with rounded end upsee 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 suppositoryremove exposed suppository from wrapperinsert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movementchildren under 12 years of age: ask a doctor <p>Other information</p> <ul style="list-style-type: none">store at 20-25°C (68-77°F) <p>Inactive ingredients methylparaben, propylparaben, topical starch</p> <p>Questions or comments? 1-800-719-9260</p> <p>**This product is not manufactured or distributed by Pfizer, distributor of Preparation H® Hemorrhoidal Suppositories. DISTRIBUTED BY FOODHOLD U.S.A., LLC, LANDOVER, MD 20785 1-877-846-9949 • ©2017 Ahold Licensing Sarl Quality guaranteed or your money back.</p>
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CAREONE HEMORRHOIDAL
cocoa butter, phenylephrine hcl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-004
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 HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	6.5 mg

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (light)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-004-53	12 in 1 CARTON	12/21/2014	
1		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	12/21/2014	

Labeler - American Sales Company (809183973)