

HEMORRHOIDAL COCOA BUTTER- hemorrhoidal suppository
NeilMed Pharmaceuticals 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.

NeilMed Hemorrhoidal Suppositories 24count

Drug Facts :

Active Ingredients (in each suppository) :

Cocoa butter 88.44%

Phenylephrine Hydrochloride 0.25%

Purpose

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 prostate gland unless directed by a doctor

Ask a doctor or pharmacist before use

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
- children under 12 years of age: ask a doctor

Stop use and ask 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)

Other information:

store at 20° - 25°C (68° - 77°F)

Inactive ingredients:

methylparaben, propylparaben, topical starch

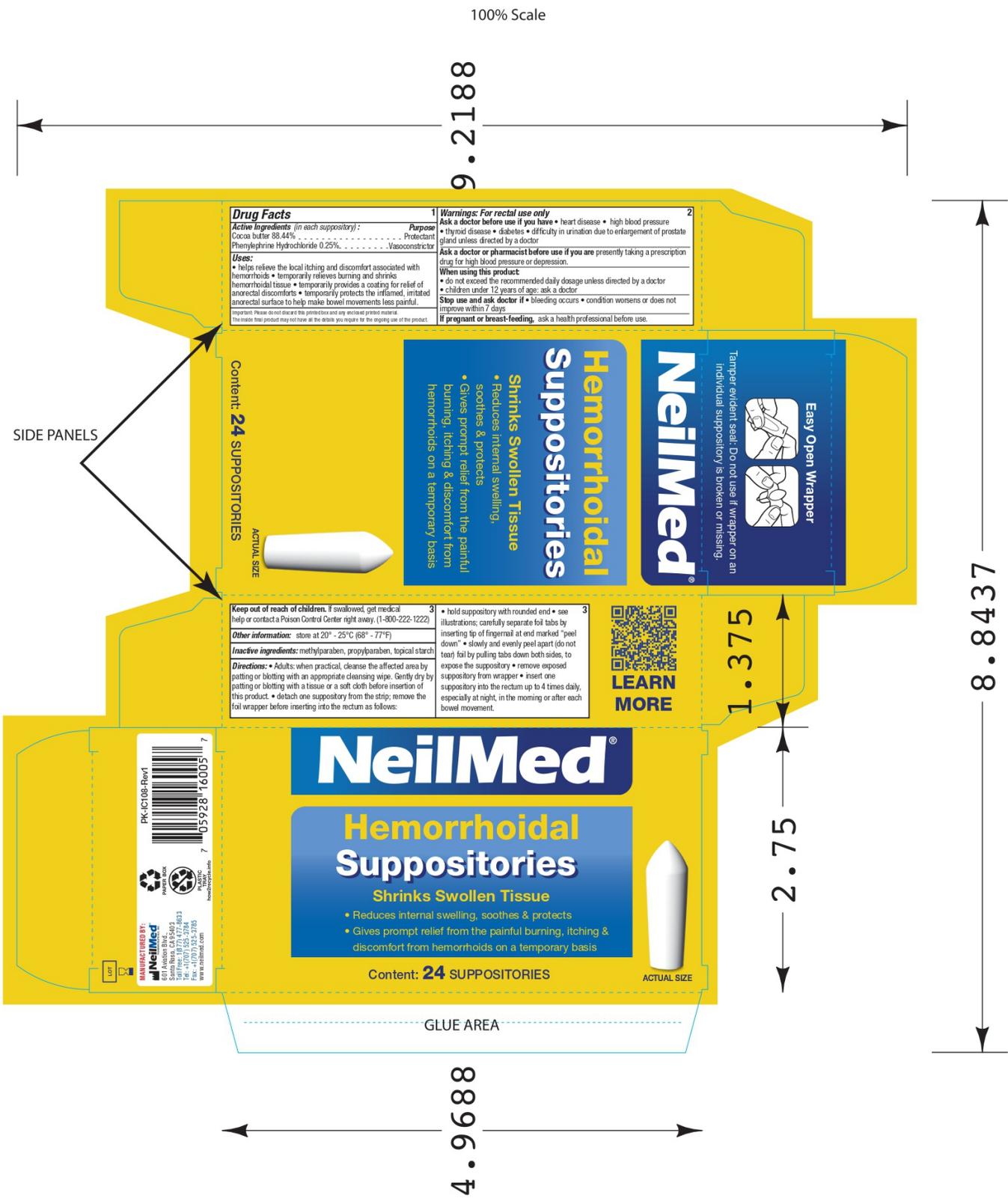
Directions:

• 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 • 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.

Shrinks Swollen Tissue

- Reduces internal swelling, soothes & protects
- Gives prompt relief from the painful burning, itching & discomfort from hemorrhoids on a temporary basis



HEMORRHOIDAL COCOA BUTTER

hemorrhoidal suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-323
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Route of Administration RECTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
COCOA BUTTER (UNII: 512OYT1CRR) (COCOA BUTTER - UNII:512OYT1CRR)	COCOA BUTTER	884.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-323-01	4 in 1 CARTON	08/24/2023	
1		6 in 1 BLISTER PACK		
1		2 g in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	08/24/2023	

Labeler - NeilMed Pharmaceuticals Inc. (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals Inc.		799295915	manufacture(13709-323)

Revised: 8/2023

NeilMed Pharmaceuticals Inc.