PREPARATION H- cocoa butter and phenylephrine hydrochloride suppository
Pfizer Consumer Healthcare

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.

PREPARATION H® HEMORRHOIDAL SUPPOSITORIES

Drug Facts

Active ingredients	***Purposes***
Cocoa butter 88.44%	Protectant
Phenylephrine HCl 0.25%	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

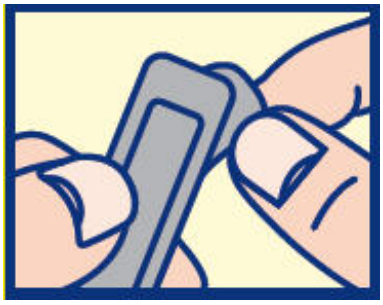
If pregnant or breast-feeding, ask a health professional before use.

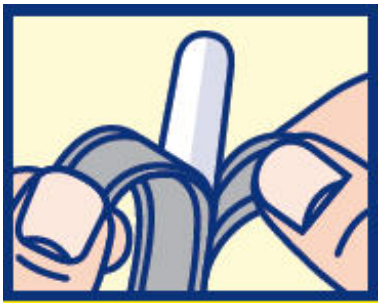
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or

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
  - as shown, 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

Questions or comments?

Call weekdays 9 AM to 5 PM EST at **1-800-99PrepH or 1-800-997-7374**

For most recent product information, visit www.preparationh.com
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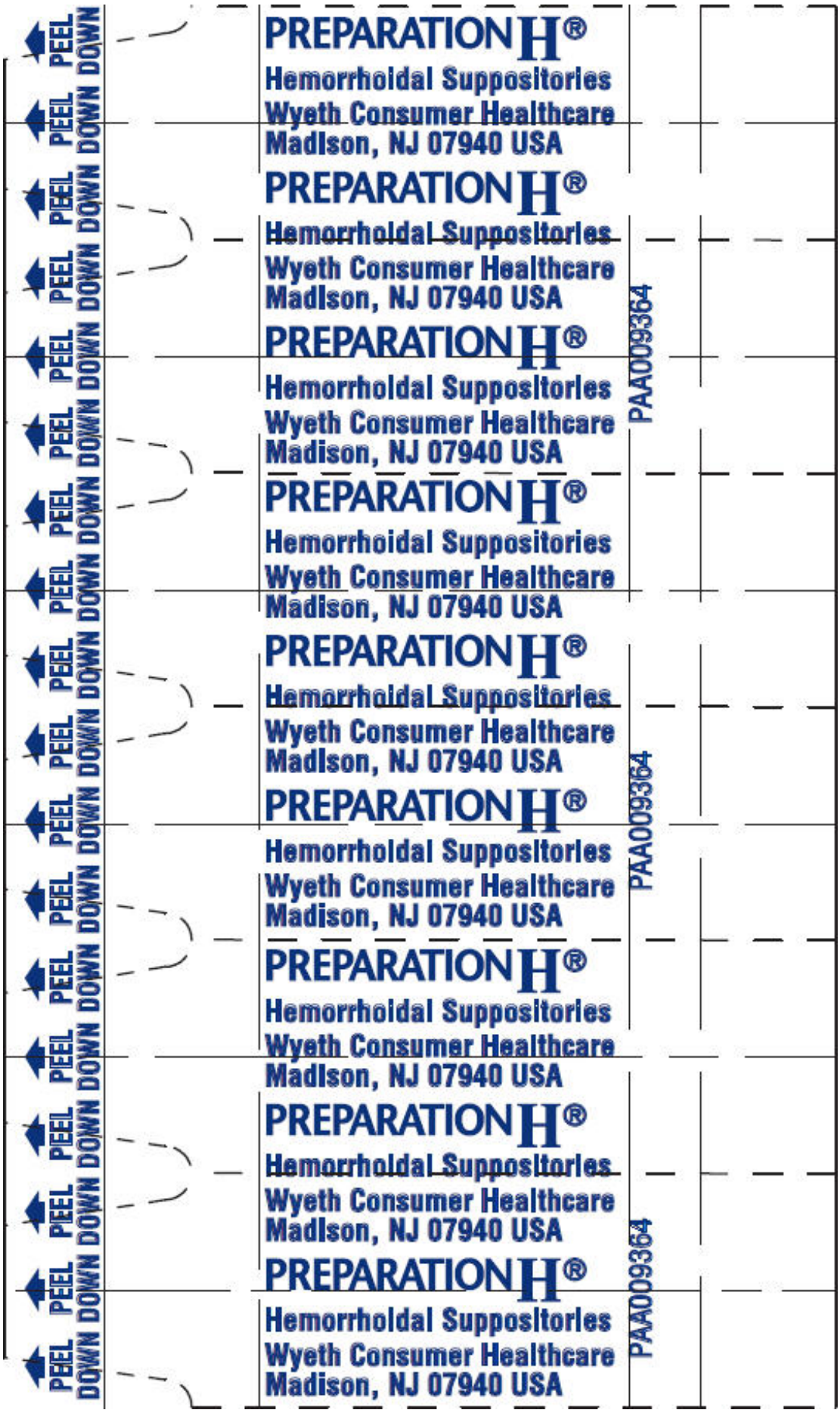
PRINCIPAL DISPLAY PANEL - 12 Suppository Blister Pack

PREPARATION H®

Hemorrhoidal Suppositories
Wyeth Consumer Healthcare
Madison, NJ 07940 USA

PAA009364



PRINCIPAL DISPLAY PANEL - 12 Suppository Blister Pack Carton

PREPARATION H®

HEMORRHOIDAL SUPPOSITORIES

Reduces Internal Swelling, Soothes and Protects

- Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Also for Nighttime Relief

12 SUPPOSITORIES

PRINCIPAL DISPLAY PANEL - 48 Suppository Blister Pack Carton

PREPARATION H®
HEMORRHOIDAL
SUPPOSITORIES

Provides Relief from
MULTIPLE SYMPTOMS

- Reduces Internal Swelling, Soothes & Protects
- Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- Also for Nighttime Relief

#1 SELLING
#1
• HEMORRHOID BRAND •

48 SUPPOSITORIES

LOT & EXP

PREPARATION H®
HEMORRHOIDAL
SUPPOSITORIES

Individually quality sealed for your protection.
Do Not Use if foil imprinted "PREPARATION H" is torn or damaged.

PREPARATION H®
HEMORRHOIDAL
SUPPOSITORIES

Provides Relief from
MULTIPLE SYMPTOMS

- ✓ Reduces Internal Swelling, Soothes & Protects
- ✓ Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- ✓ Also for Nighttime Relief

#1 SELLING #1 HEMORRHOID BRAND

48 SUPPOSITORIES

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PREPARATION H®
HEMORRHOIDAL
SUPPOSITORIES

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FPO

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UNVARNISHED AREA

PREPARATION H®
HEMORRHOIDAL
SUPPOSITORIES

Provides Relief from
MULTIPLE SYMPTOMS

- ✓ Reduces Internal Swelling, Soothes & Protects
- ✓ Prompt Soothing Relief from Painful Burning, Itching and Discomfort
- ✓ Also for Nighttime Relief

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HEMORRHOIDAL
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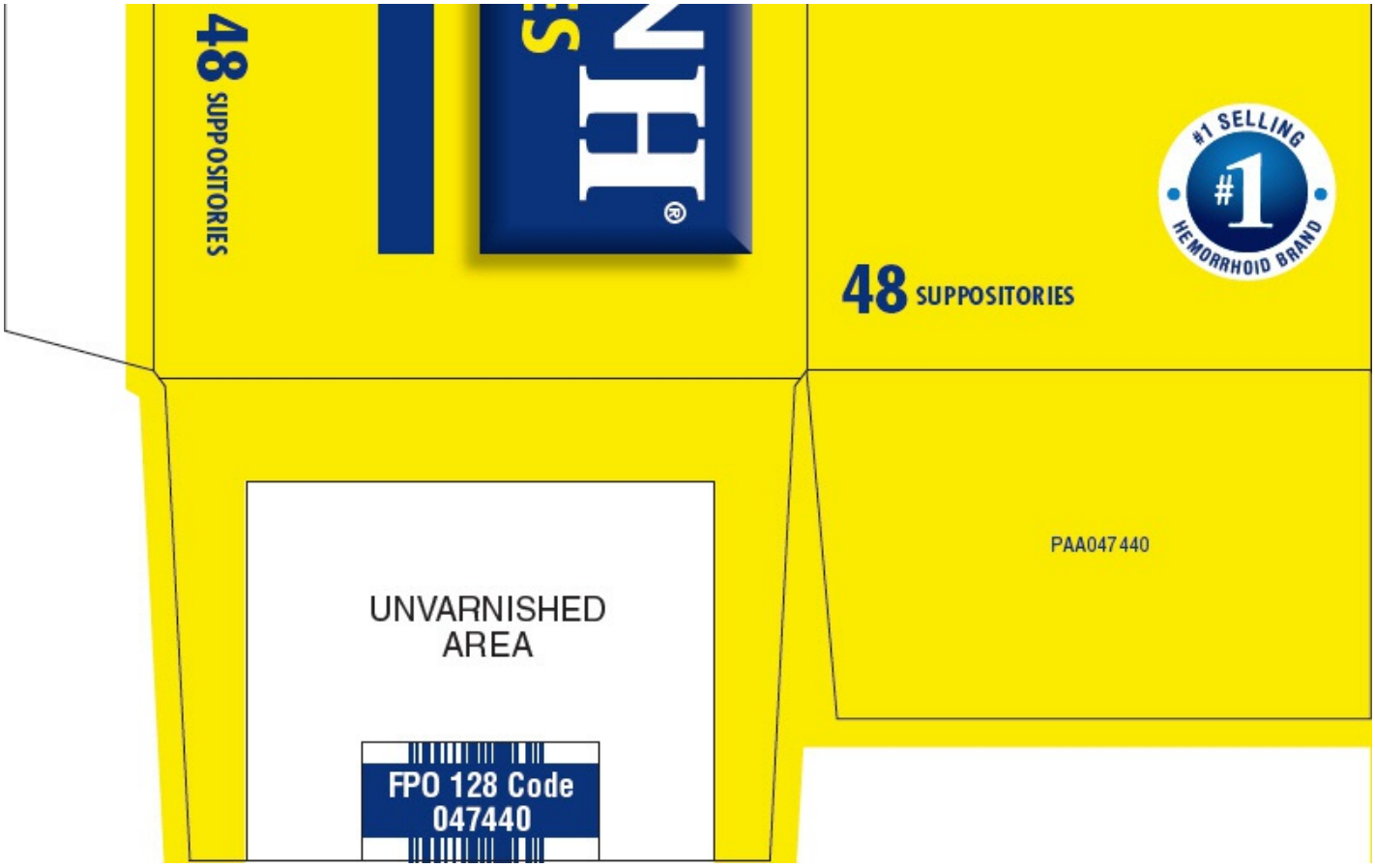

PREPARATION H

cocoa butter, phenylephrine hydrochloride suppository

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0573-2883
Route of Administration	RECTAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (COCOA BUTTER)	COCOA BUTTER	2211 mg
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN	
METHYLPARABEN	
PROPYLPARABEN	

Product Characteristics

Color	YELLOW (Light yellow)	**Score**	no score

Shape	BULLET (Bullet shaped suppository)	**Size**	150mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2883-10	12 in 1 CARTON		
1		1 in 1 BLISTER PACK; Combination Product Type = C112160		
2	NDC:0573-2883-20	24 in 1 CARTON		
2		1 in 1 BLISTER PACK; Combination Product Type = C112160		
3	NDC:0573-2883-30	48 in 1 CARTON		
3		1 in 1 BLISTER PACK; Combination Product Type = C112160		
4	NDC:0573-2883-55	56 in 1 CARTON		
4		1 in 1 BLISTER PACK; Combination Product Type = C112160		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	01/05/2004	

PREPARATION H

cocoa butter, phenylephrine hydrochloride suppository

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0573-2880
Route of Administration	RECTAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (COCOA BUTTER)	COCOA BUTTER	2211 mg
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN	
METHYLPARABEN	
PROPYLPARABEN	

Product Characteristics

Color	YELLOW (Light yellow)	**Score**	no score
Shape	BULLET (Bullet shaped suppository)	**Size**	150mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2880-31	48 in 1 CARTON		
1		1 in 1 BLISTER PACK; Combination Product Type = C112160		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	01/05/2004	

Labeler - Pfizer Consumer Healthcare (828831730)

Revised: 9/2014 Pfizer Consumer Healthcare