

PHENYLEPHRINE HYDROCHLORIDE - phenylephrine hydrochloride suppository
Walgreen 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.

DRUG FACTS

ACTIVE INGREDIENTS

Cocoa butter, 85.5%

Phenylephrine HCl, 0.25%

Shark liver oil, 3.0%

PURPOSE

protectant

vasoconstrictor

protectant

USES

- Temporarily shrinks hemorrhoidal tissue
- Temporarily relieves itching burning and discomfort associated with hemorrhoids

WARNINGS

For rectal use only.

Ask a doctor before use if you have

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

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.

Stop use and ask a doctor if

- you experience bleeding
- condition worsens or does not improve within 7 days.

These may be signs of a serious condition.

If pregnant or breastfeeding

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 tissue. Gently dry by patting or blotting with toilet tissue or soft cloth before insertion of this product.
- Detach one suppository from strip
- Remove wrapper before inserting into rectum
- Hold suppository with rounded end up and insert tip of fingernail at end marked "peel down"
- Carefully peel film slowly and evenly down both sides to expose suppository
- Insert one suppository into rectum up to 4 times daily especially at night and morning or after each bowel movement

Children under 12 years: ask a doctor

STORAGE

Store in a cool place or at room temperature but not over 86° F.

INACTIVE INGREDIENTS

methylparaben, propylparaben, starch

BOX INFORMATION - 12 count

Walgreens

NDC 0363-0394-53

**Hemorrhoidal
Suppositories**

- Temporary relief of burning, itching and discomfort
- Shrinks swelling of irritated hemorrhoidal tissue
- Protects irritated tissue
- Also provides nighttime relief

Compare to *Preparation H Suppositories*® active ingredients*

12 SUPPOSITORIES

FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-EVIDENT SEALED PLASTIC WRAPPER. DO NOT USE IF PLASTIC WRAPPER IS TORN OR OPEN.

*This product is not manufactured or distributed by Wyeth Consumer Healthcare, Inc., owner of the

registered trademark Preparation H®.

Distributed by Walgreens Company, Deerfield, IL 60015-4616
100% Satisfaction Guaranteed www.walgreens.com

ITEM 596682
UPC FPO
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Walgreens
The Brand America Trust®

Hemorrhoidal Suppositories

Temporary relief of the burning, itching and discomfort associated with hemorrhoids

NDC 0363-0394-63

Walgreens
The Brand America Trust®

Hemorrhoidal Suppositories

• Temporary relief of burning, itching and discomfort
• Shrinks swelling of irritated hemorrhoidal tissue
• Protects irritated tissue
• Also provides nighttime relief

**Compare to Preparation H®
Suppositories active ingredients***

12 SUPPOSITORIES

Drug Facts (continued)

Other information
Store in a cool place or at room temperature but not over 86° F.

Inactive ingredients
methylparaben, propylparaben, starch

Drug Facts (continued)

For your safety, suppositories are packaged in tamper-evident sealed plastic wrappers. Do not use if plastic wrapper is torn or open.

Pharmacist Recommended

Drug Facts

Active ingredient (in each suppository)
Coconut butter, 85.5%
Phenylephrine HCl, 0.25%
Shark liver oil, 3.0%
Protectant
Vasoprotector
Protectant

Purpose
■ condition worsens or does not improve within 7 days. These may be signs of a serious condition.
■ pregnant or breastfeeding, 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 tissue. Gently dry by patting or blotting with toilet tissue or soft cloth before insertion of this product.
■ Detach one suppository from strip.
■ Remove wrapper before inserting into rectum.
■ Hold suppository with rounded end up and insert tip of finger nail at end marked "point down".
■ Carefully push film slowly and evenly down both sides to expose suppository.
■ Insert one suppository into rectum up to 4 times daily especially at night and morning or after each bowel movement.

Children under 12 years: ask a doctor.

Warnings
For rectal use only.
Ask a doctor before use if you have
■ heart disease
■ high blood pressure
■ diabetes
■ difficulty in urination due to enlargement of the prostate gland.

Uses
■ Temporarily soothes hemorrhoidal tissue
■ Temporarily relieves itching, burning and discomfort associated with hemorrhoids

Stop use and ask a doctor if ■ you experience bleeding

When using this product do not exceed the recommended daily dosage.

Ask a doctor or pharmacist before use if you are pregnant taking a prescription drug for high blood pressure or depression.

BOX INFORMATION - 24 count

Walgreens

NDC 0363-0394-62

Hemorrhoidal Suppositories

- Temporary relief of burning, itching and discomfort
- Shrinks swelling of irritated hemorrhoidal tissue
- Protects irritated tissue
- Also provides nighttime relief

Compare to Preparation H Suppositories® active ingredients*

24 SUPPOSITORIES

FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-EVIDENT SEALED PLASTIC WRAPPER. DO NOT USE IF PLASTIC WRAPPER IS TORN OR OPEN.

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PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0394
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
cocoa butter (UNII: 512OYT1CRR) (cocoa butter - UNII:512OYT1CRR)	cocoa butter	2077 mg
phenylephrine hydrochloride (UNII: 04JA59 TNSJ) (phenylephrine - UNII:1WS297W6MV)	phenylephrine hydrochloride	6 mg

shark liver oil (UNII: 4B24275HEU) (shark liver oil - UNII:4B24275HEU)	shark liver oil	73 mg
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Inactive Ingredients

Ingredient Name	Strength
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
starch, corn (UNII: O8232NY3SJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0394-53	12 in 1 BOX		
2	NDC:0363-0394-62	24 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/01/2005	

Labeler - Walgreen Company (008965063)

Revised: 2/2010

Walgreen Company