

PHENYLEPHRINE HYDROCHLORIDE - phenylephrine hydrochloride suppository
H and P Industries, Inc. dba Triad Group

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

PACKAGE INFORMATION

NDC 50730-4812-0

Live Better

Hemorrhoidal

Suppositories

PHENYLEPHRINE HCL 0.25%

- Temporary relief of burning, itching and discomfort
- Provides nighttime relief
- Shrinks swelling of irritated hemorrhoidal tissue
- Protects irritated tissue
- Easy to open

12 Suppositories

DISTRIBUTED BY OMNIPOINT, INC.

2 PARAGON DRIVE, MONTVALE, NJ 07654

Live Better products provide a simple way to look after yourself and your family. All of our products are crafted from high quality ingredients to exacting standards.

Live Better is a great way to meet the health needs of your busy lifestyle. Live Better helps you be better.

Live Better, for life.

FOR YOUR SAFETY, SUPPOSITORIES ARE PACKAGED IN TAMPER-EVIDENT SEALED PLASTIC WRAPPER.

DO NOT USE IF PLASTIC WRAPPER IS TORN OR OPEN.



Rev. B1208

Hemorrhoidal Suppositories

PHENYLEPHRINE HCL 0.25% 12 Suppositories

Hemorrhoidal Suppositories

No Print/Dark Colors Allowed Lot/Exp Channel



Hemorrhoidal Suppositories

PHENYLEPHRINE HCL 0.25%

- TEMPORARY RELIEF OF BURNING, ITCHING AND DISCOMFORT
- PROVIDES NIGHTTIME RELIEF
- SHRINKS SWELLING OF IRRITATED HEMORRHOIDAL TISSUE
- PROTECTS IRRITATED TISSUE
- EASY TO OPEN

12 Suppositories



UPC-A PPO



QUALITY ASSURED



Hemorrhoidal Suppositories

33-4812AP-C

Drug Facts

Active ingredient (in each suppository)

Phenylephrine HCL 0.25%

Excipients: Cocoa butter 85.5%, Vasoconstrictor, Shink liver oil 3.0%

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.

Stop use and ask a doctor if:

- you experience bleeding
- condition worsens
- does not improve within 7 days. These may be signs of a serious condition.

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.

Drug Facts (continued)

Purpose

Product: Vasoconstrictor

Directions

Adults: When practical, cleanse the affected area by patting or blotting with an appropriate cleansing tissue. Empty dry by patting or blotting with toilet tissue or soft cloth before insertion of the 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 "peel down".

■ Carefully peel film slowly and evenly down both sides to expose suppository morning or after each bowel movement.

■ Insert one suppository into rectum up to 4 times daily, especially at night and Children under 12 years: ask a doctor.

Other information

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

Inactive ingredients methylparaben, propylparaben, starch

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PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-4812
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: 04JA59TNSJ) (phenylephrine - UNII:1WS297W6MV)	phenylephrine hydrochloride	6 mg
shark liver oil (UNII: 4B24275HEU) (shark liver oil - UNII:4B24275HEU)	shark liver oil	73 mg

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:50730-4812-0	12 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/01/2009	

Labeler - H and P Industries, Inc. dba Triad Group (050259597)

Revised: 12/2009

Hand P Industries, Inc. dba Triad Group