

COCOA BUTTER, PHENYLEPHRINE HYDROCHLORIDE, SHARK LIVER OIL - cocoa butter, phenylephrine hydrochloride, shark liver oil 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 50730-1481-1

Cat. No. 10-14812

TRIAD®

**HEMORRHOIDAL
SUPPOSITORIES**

Temporarily relieves itching and discomfort associated with hemorrhoids
Individually wrapped unit dose

12 suppositories

Triad Group, Inc.
Brookfield, WI 53045 USA

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

PLASTIC WRAPPER.
DO NOT USE IF PLASTIC WRAPPER IS TORN OR OPEN.

Drug Facts

Active ingredient (in each suppository)	Purpose
Cocoa butter, 85.5%	Protectant
Phenylephrine HCl, 0.25%	Vasoconstrictor
Shark liver oil, 3.0%	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	■ 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

Drug Facts (continued)

■ condition worsens or does not improve within 7 days. There 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.

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 the product.

- Detach one suppository from strip
- Remove wrapper before inserting into rectum
- Hold suppository with rounded end up and insert tip of finger at and marked "pud 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.

Drug Facts (continued)

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

Inactive ingredients
methylparaben, propylparaben, starch



Rev. A



HEMORRHOIDAL SUPPOSITORIES

Temporarily relieves itching and discomfort associated with hemorrhoids
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HEMORRHOIDAL SUPPOSITORIES

12 suppositories

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Triad Group, Inc. MADE IN USA
Brookfield, WI 53045 www.triad-group.net



(01) 10350730148112

HEMORRHOIDAL SUPPOSITORIES

12 suppositories

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COCOA BUTTER, PHENYLEPHRINE HYDROCHLORIDE, SHARK LIVER OIL

cocoa butter, phenylephrine hydrochloride, shark liver oil suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50730-1481
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: A28C7H9T)	
propylparaben (UNII: Z8IX2SC1OH)	
starch, corn (UNII: O8232NY3SJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-1481-1	12 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/06/2004	

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

Name	Address	ID/FEI	Business Operations
H and P Industries, Inc. dba Triad Group		050259597	manufacture

Revised: 11/2009

Hand P Industries, Inc. dba Triad Group