# MINERAL OIL, PETROLATUM, PHENYLEPHRINE HYDROCHLORIDE, SHARK LIVER OIL - mineral oil, petrolatum, phenylephrine hydrochloride, shark liver oil ointment 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.

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### **DRUG FACTS**

### **ACTIVE INGREDIENTS**

Mineral oil, 14%

Petrolatum, USP 71.9% Phenylephrine HCI, 0.25%

Shark liver oil, 3.0%

### **PURPOSE**

**Protectant** 

**Protectant** 

Vasoconstrictor

Protectant

### **USES**

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

### **WARNINGS**

For external and/or intrarectal use only.

### Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
- 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.
- do not use this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a doctor promptly.

### 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 application of this ointment.
- Apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement.

### For intrarectal use:

- Before applying, remove protective cover from applicator. Attach applicator to tube. Lubricate applicator well and then gently insert applicator into the rectum. Thoroughly clean applicator after each use and replace protective cover.
- Also apply ointment to external area.

**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**

beeswax, benzoic acid, BHA, corn oil, glycerin, lanolin, lanolin alcohol, methylparaben, paraffin, propylparaben, thyme oil, tocopherol, water

### PACKAGE INFORMATION

TRIAD®

HEMORRHOIDAL OINTMENT

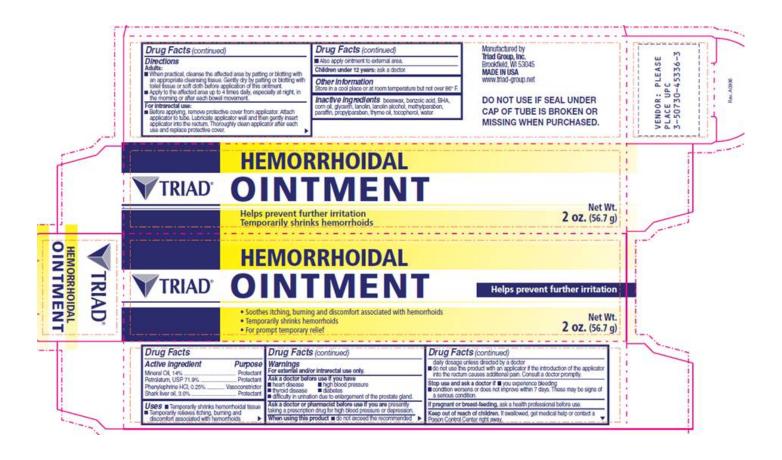
Helps prevent further irritation Temporarily shrinks hemorrhoids

- Soothes itching, burning and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoids
- For prompt temporary relief

Net wt. 2 oz. (56.7 g)

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

DO NOT USE IF SEAL UNDER CAP OF TUBE IS BROKEN OR MISSING WHEN PURCHASED.



# MINERAL OIL, PETROLATUM, PHENYLEPHRINE HYDROCHLORIDE, SHARK LIVER OIL mineral oil, petrolatum, phenylephrine hydrochloride, shark liver oil ointment Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50730-4536 Route of Administration RECTAL, TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

light mineral oil (UNII: N6K5787QVP) (light mineral oil - UNII:N6K5787QVP)	light mineral oil	140 mg in 1 g
petrolatum (UNII: 4T6H12BN9U) (petrolatum - UNII:4T6H12BN9U)	pe tro la tum	719 mg in 1 g
phenylephrine hydrochloride (UNII: 04JA59TNSJ) (phenylephrine - UNII:1WS297W6MV)	phe nyle phrine hydro chlo ride	2.5 mg in 1 g
shark liver oil (UNII: 4B24275HEU) (shark liver oil - UNII:4B24275HEU)	shark liver oil	30 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WAX, YELLOW (UNII: 2ZA36H0S2V)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	
CORN OIL (UNII: 8470G57WFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PARAFFIN (UNII: 1900 E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
THYMUS OIL (UNII: M86Z5G7U0L)	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50730-4536-0	1 in 1 BOX		
1	56.7 g in 1 TUBE, WITH APPLICATOR		

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/01/2005	

# 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	<b>Business Operations</b>	
Hand P Industries, Inc. dba Triad Group		050259597	manufacture	