

**LEADER HEMORRHOIDAL - mineral oil, petrolatum, phenylephrine hcl, shark liver oil ointment**

**CARDINAL HEALTH**

*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	Purpose
Mineral oil 14% .....	Protectant
Petrolatum 71.9% .....	Protectant
Phenylephrine HCL 0.25% .....	Vasoconstrictor
Shark liver oil 3.0% .....	Protectant

**Uses**

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieves burning
- 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 external and/or intrarectal use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

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

When using this product do not use more than the recommended daily dosage

Stop use and ask a doctor if

- bleeding occurs
- condition gets worse or does not get better within 7 days
- introduction of the applicator into the rectum causes additional pain

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- children under 12 years of age: ask a doctor
- adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe

- gently dry by patting or blotting with a tissue or a soft cloth before applying
- when first opening tube, remove foil seal
- for intrarectal use: remove protective cover from applicator and attach to tube
- lubricate applicator well, then gently insert applicator into the rectum
- thoroughly clean applicator and replace protective cover after each use
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- also apply ointment to external area

Other information

Store at 20° to 25°C (68° to 77°F)

Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

BHA, concentrated glycerin, glyceryl monosterate, methylparaben, propylparaben, purified lanoline, purified water, thyme oil red

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

CIN2312940

[www.myleader.com](http://www.myleader.com)

1-800-200-6313

Made in Korea

**Drug Facts (continued)**

Ask a doctor before use if you have ■ heart disease ■ high blood pressure  
 ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland

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

When using this product do not use more than the recommended daily dosage

Stop use and ask a doctor if ■ bleeding occurs  
 ■ condition gets worse or does not get better within 7 days  
 ■ introduction of the applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a physician before use. ▶

**Drug Facts (continued)**

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

**Directions** ■ children under 12 years of age: ask a doctor  
 ■ adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe  
 ■ gently dry by patting or blotting with a tissue or a soft cloth before applying  
 ■ when first opening tube, remove foil seal  
 ■ for intrarectal use: remove protective cover from applicator and attach to tube  
 ■ lubricate applicator well, then gently insert applicator into the rectum  
 ■ thoroughly clean applicator and replace protective cover after each use

**Drug Facts (continued)**

■ apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement  
 ■ also apply ointment to external area

**Other information** store at 20° to 25° C (68° to 77° F)

**Inactive ingredients** benzoic acid, BHA, BHT, methylparaben, paraffin, propylparaben, thyme oil, glyceryl stearate, glycerin, absorb refined lanoline, purified water

**TAMPER-EVIDENT: Do not use if "FOIL SEAL" is broken or missing.**

DISTRIBUTED BY CARDINAL HEALTH  
 DUBLIN, OHIO 43017  
 CN 2312940  
 www.myleader.com  
 1-800-200-6313

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.



0 96295 06895 5  
 Made in Korea

NDC 37205-405-16





## Hemorrhoidal Ointment

### With Applicator

NET WT. 2 OZ (56 g)

Compare to Preparation H®

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Mineral oil 14%.....	Protectant
Petrolatum 71.9%.....	Protectant
Phenylephrine HCl 0.25%.....	Vasoconstrictor
Shark liver oil 3.0%.....	Protectant

**Drug Facts (continued)**

**Uses** ■ helps relieve the local itching and discomfort associated with hemorrhoids  
 ■ temporarily shrinks hemorrhoidal tissue and relieves burning  
 ■ 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 external and/or intrarectal use only

Enter section text here

## LEADER HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hcl, shark liver oil ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-405
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g

<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	19 mg in 1 g
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
<b>SHARK LIVER OIL</b> (UNII: 4B24275HEU) (SHARK LIVER OIL - UNII:4B24275HEU)	SHARK LIVER OIL	30 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>THYME OIL</b> (UNII: 2UK410MY6B)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-405-16	1 in 1 CARTON		
1		56 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	05/01/2012	

**Labeler** - CARDINAL HEALTH (097537435)

Revised: 5/2012

CARDINAL HEALTH