

LEADER HEMORRHOIDAL - phenylephrine hydrochloride, hard fat suppository
CARDINAL HEALTH, INC.

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.

Hemorrhoidal Suppositories

ACTIVE INGREDIENT

Hard Fat 85.5%
Phenylephrine HCl 0.25%

PURPOSE

- Protectant
- Vasoconstrictor

USES

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily relieves burning and shrinks hemorrhoidal tissue
- 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 rectal use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to an enlarged prostate

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 use more than directed

Stop use and ask a doctor if

- symptoms get worse or do not get better in 7 days
- bleeding occurs

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, clean the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with tissue or a soft cloth before insertion of the product.

- detach 1 suppository from the strip; remove wrapper before inserting into the rectum as follows:



- hold suppository with pointed end up
 - carefully separate tabs with fingernail
 - slowly pull apart by pulling tabs down on both sides
 - remove suppository from wrapper
- insert one suppository into the rectum up to 4 times daily, especially at night, in the morning or after each bowel movement
 - children under 12 years: ask a doctor

OTHER INFORMATION

- store at 20-25°C (68-77°F)

INACTIVE INGREDIENT

cod liver oil, corn starch, methylparaben, propylparaben

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 37205-715-16

Compare to Preparation H® active ingredients

LEADER HEMORRHOIDAL SUPPOSITORIES

Prompt Relief

For Temporary Relief From Pain and Itching of Hemorrhoids

12 ADULT SUPPOSITORIES

Satisfaction Guaranteed

Drug Facts (continued)

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Stop use and ask a doctor if

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- bleeding occurs

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, clean the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with tissue or a soft cloth before insertion of the product.

Drug Facts (continued)

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Inactive Ingredients: cod liver oil, corn starch, methylparaben, propylparaben

DISTRIBUTED BY
 CARDINAL HEALTH
 DUBLIN, OHIO 43017
 CIN 1963214
 www.myleader.com
 1-800-200-6313
 MADE IN USA

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

*Preparation H® is a registered trademark of Wyeth Consumer Healthcare

80% UPC TRUNCATED
 0-96295-10820-0

Tamper Evident: For your safety suppositories are packaged in "Tamper-Evident" sealed foil. Do not use if foil is torn or open

NDC 37205-715-16



Compare to
 Preparation H®
 active ingredients*

Hemorrhoidal Suppositories

PROMPT RELIEF

For Temporary Relief From Pain and Itching of Hemorrhoids



12 ADULT SUPPOSITORIES

Drug Facts

Active ingredients

(in each rectal suppository)

- Hard fat 85.5%.....Protectant
- Phenylephrine HCl 0.25%.....Vasoconstrictor

Purpose

Drug Facts (continued)

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LEADER HEMORRHOIDAL

phenylephrine hydrochloride, hard fat suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-715
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5.77 mg
Fat, Hard (UNII: 8334LX7S21) (Fat, Hard - UNII:8334LX7S21)	Fat, Hard	1881 mg

Inactive Ingredients

Ingredient Name	Strength
Cod Liver Oil (UNII: BBL281NWFG)	
Starch, Corn (UNII: O8232NY3SJ)	
Methylparaben (UNII: A218C7H19T)	
Propylparaben (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-715-16	12 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/12/2009	

Labeler - CARDINAL HEALTH, INC. (097537435)**Registrant** - G&W Laboratories, Inc. (001271188)**Establishment**

Name	Address	ID/FEI	Business Operations
G&W Laboratories, Inc.		001271188	MANUFACTURE

Revised: 1/2012

CARDINAL HEALTH, INC.