

LEADER- phenylephrine hydrochloride and witch hazel cream

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

Phenylephrine hydrochloride 0.25%

Witch hazel 50.0%

Vasoconstrictor

Astringent

Uses

- temporarily relieves irritation and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas

Warnings

For external use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to an enlarged 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 put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor If

- bleeding occur
- condition gets worse or does not improve within 7 days

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 and gently dry the affected area by patting or blotting with an

- appropriate cleansing tissue or soft cloth before applying gel
- when first opening the tube, puncture foil seal with top end of cap
 - apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
 - **Children under 12 years of age:** ask a doctor

Other information

- store at 20°-25°C (68°-77°F)
- for lot number and expiration date, see crimp of tube or see box

Inactive ingredients

aloe barbadensis leaf juice, disodium EDTA, hydroxyethylcellulose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, tocopheryl acetate (Vitamin E)

Principal Display Panel - Carton Label

NDC 49781-091-01

LEADER®

Hemorrhoidal Cooling Gel

Relief from intense burning & itching

Relieves external discomfort

Enriched with Aloe

NET WT 0.9 OZ (26g)



LEADER

phenylephrine hydrochloride and witch hazel cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4978 1-09 1
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
phenylephrine hydrochloride (UNII: 04JA59 TNSJ) (phenylephrine - UNII:1WS29 7W6 MV)	phenylephrine hydrochloride	2.5 mg in 1 L
witch hazel (UNII: 10 1I4J0 U34) (witch hazel - UNII:10 1I4J0 U34)	witch hazel	500 mg in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z83H0 X)	
edetate disodium (UNII: 7FLD9 1C86 K)	
hydroxyethyl cellulose (100 mpa.s at 2%) (UNII: R33S7TK2EP)	
methylparaben (UNII: A2I8 C7HI9 T)	
polyorbate 80 (UNII: 6OZP39 ZG8 H)	
propylene glycol (UNII: 6DC9Q 167V3)	
propylparaben (UNII: Z8 IX2SC 1OH)	

water (UNII: 059QF0KO0R)	
sodium citrate (UNII: 1Q73Q2JULR)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-091-01	1 in 1 CARTON	04/28/2014	
1		0.026 L in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/28/2014	

Labeler - Cardinal Health (097537435)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials		947484713	MANUFACTURE(49781-091)

Revised: 1/2018

Cardinal Health