

LEADER- glycerin, petrolatum, phenylephrine hydrochloride and pramoxine hydrochloride 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

Glycerin 14.4%

Petrolatum 15%

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

Purposes

Protectant

Protectant

Vasoconstrictor

Local anesthetic

Uses

- helps relieve local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporarily relieves burning
- 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 unless directed by a doctor
- 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 occurs

- 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
- 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

cetearyl alcohol, cetyl alcohol, glycerol monostearate, mineral oil, peg 40 castor oil, propylene glycol, purified water, stearyl alcohol, tocopheryl acetate (Vitamin E)

Principal Display Panel - Carton Label

NDC 49781-090-01

LEADER[®]

MAXIMUM STRENGTH

Hemorrhoidal Cream

Rapid soothing pain relief from burning, itching and discomfort Protects irritated tissue

NET WT 1 OZ (28g)



Principal Display Panel - Tube Label

NDC 49781-090-01

LEADER®

MAXIMUM STRENGTH

Hemorrhoidal Cream

Rapid soothing pain relief from burning, itching and discomfort Protects irritated tissue

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Compare to
Preparation H®
Maximum Strength Cream
active ingredients*

MAXIMUM STRENGTH

Hemorrhoidal Cream

Rapid soothing pain relief from burning, itching and discomfort
Protects irritated tissue



NET WT 1 OZ (28g)

Active ingredients: Glycerin 14.4%, Petrolatum 15%, Phenylephrine HCl 0.25%, Pramoxine HCl 1%.

Use: Helps relieve local itching and discomfort associated with hemorrhoids.

Warnings: For external use only. Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression. Do not exceed the recommended daily dosage unless directed by a doctor. If condition worsens or if symptoms persist for more than 7 days, discontinue use and consult a physician.

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 application. 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).

Inactive ingredients: cetearyl alcohol, cetyl alcohol, glycerol monostearate, mineral oil, peg 40 castor oil, propylene glycol, purified water, stearyl alcohol, tocopheryl acetate (Vitamin E).

*This product is not manufactured or distributed by Wyeth Consumer Healthcare, the owner of the registered trademark Preparation H®.

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

CIN 4952107

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.

LEADER

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-090
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	144 mg in 1 L
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	150 mg in 1 L
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 1 L
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	10 mg in 1 L

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Mineral Oil (UNII: T5L8T28FGP)	
Peg-40 Castor Oil (UNII: 4ERD2076EF)	
Water (UNII: 059QF0K00R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
.ALPHA.-Tocopherol Acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-090-01	1 in 1 CARTON	04/28/2014	
1		0.028 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
PJ Noyes Company		018927392	MANUFACTURE(49781-090)

Revised: 1/2018

Cardinal Health