

**SELECT BRAND HEMORRHOID- glycerin, petrolatum, phenylephrine hydrochloride, pramoxine hydrochloride cream**  
**L&R Distributors, 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.*

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**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 - 1oz Carton Label**

NDC 15127-590-00

A medicated cream for local application as an aid in the relief of the discomfort due to rectal irritation.

*select brand*<sup>®</sup>

the lower price name brand

**HEMORRHOIDAL  
CREAM**

**MAXIMUM STRENGTH**

\*Compare to the active ingredients in Preparation H<sup>®</sup> Maximum Strength Cream

Net Wt. 1 oz (28g)



## SELECT BRAND HEMORRHOID

glycerin, petrolatum, phenylephrine hydrochloride, pramoxine hydrochloride cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:15127-590
<b>Route of Administration</b>	RECTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	10 mg in 1 g
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	10 mg in 1 g
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	20 mg in 1 g
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	22 mg in 1 g
<b>Mineral Oil</b> (UNII: T5L8T28FGP)	69 mg in 1 g

<b>Peg-40 Castor Oil</b> (UNII: 4ERD2076EF)	10 mg in 1 g
<b>Water</b> (UNII: 059QF0KO0R)	500.5 mg in 1 g
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	20 mg in 1 g
<b>Stearyl Alcohol</b> (UNII: 2KR89I4HIY)	20 mg in 1 g
<b>.ALPHA.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	10 mg in 1 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-590-00	1 in 1 CARTON	03/01/2014	
1		28 g 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	03/01/2014	

**Labeler** - L&R Distributors, Inc. (012578514)

### Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials		947484713	MANUFACTURE(15127-590)

Revised: 1/2018

L&R Distributors, Inc.