

**REXALL HEMORRHOIDAL- glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, and petrolatum cream**  
**Dolegencorp,LLC**

-----  
**Rexall® Hemorrhoidal Cream**  
**Topical**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purposes</i></b>
Glycerin 14.4%	Protectant
Petrolatum 15%	Protectant
Phenylephrine hydrochloride 0.25%	Vasoconstrictor
Pramoxine hydrochloride 1%	Local anesthetic

**Uses**

- temporarily relieves pain, soreness, and burning
- helps relieve local itching and discomfort associated with hemorrhoids
- temporarily 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 external use only.**

**Ask a doctor before use if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty urinating due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are** 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 into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

- bleeding occurs
- the condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain,

or other symptoms develop or increase

**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: 800-222-1222.

## Directions

### Adults:

- when practical, cleanse affected area by patting or blotting with appropriate cleansing wipe. Gently dry by patting or blotting with tissue or soft cloth before applying cream.
- when first opening tube, remove foil seal
- apply externally or in lower portion of anal canal only
- apply externally to affected area up to 4 times daily, especially at night, in the morning, or after each bowel movement
- for application in lower anal canal; remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into anus
- thoroughly cleanse dispensing cap after each use, and replace cover
- **Children under 12 years:** ask a doctor

### Other information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

### Inactive ingredients

aloe barbadensis leaf juice, BHA, cetyl alcohol, citric acid, disodium EDTA, glyceryl stearate, laureth-23, mineral oil, panthenol, phenoxy ethenol, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium carboxymethylcellulose, steareth-2, steareth-20, stearyl alcohol, tocopherol (vitamin E) acetate, xanthan gum

## PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

NDC 55910-331-24

Since 1903

Rexall®

MAXIMUM STRENGTH

Hemorrhoidal Cream

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

NET WT 1 OZ (28 g)



## REXALL HEMORRHOIDAL

glycerin, phenylephrine hydrochloride, pramoxine hydrochloride, and petrolatum cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-331
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Glycerin</b> (UNII: PDC6A3C00X) (Glycerin - UNII:PDC6A3C00X)	Glycerin	0.144 mg in 1 g
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	0.0025 mg in 1 g
<b>Pramoxine Hydrochloride</b> (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	0.1 mg in 1 g
<b>Petrolatum</b> (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	0.15 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Butylated Hydroxyanisole</b> (UNII: REK4960K2U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Laureth-23</b> (UNII: N72LMW566G)	
<b>Mineral Oil</b> (UNII: T5L8T28FGP)	
<b>Panthenol</b> (UNII: WW9CM0067Z)	
<b>Propyl Gallate</b> (UNII: 8D4SNN7V92)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Steareth-2</b> (UNII: V56DFE46J5)	
<b>Steareth-20</b> (UNII: L0Q8IK9E08)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4H1Y)	
<b>Tocopherol</b> (UNII: R0ZB2556P8)	
<b>.Alpha.-Tocopherol</b> (UNII: H4N855PNZ1)	
<b>Water</b> (UNII: 059QF0K00R)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-331-24	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 drug	M015	03/01/2014	

**Labeler** - Dolegencorp,LLC (068331990)

## Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(55910-331)