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

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.

Rexall® Hemorrhoidal Cream
Topical

Drug Facts

Active ingredients	***Purposes***
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, pheoxy 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

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-331
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	0.144 mg in 1 g
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	0.0025 mg in 1 g
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	0.1 mg in 1 g
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	0.15 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Butylated Hydroxyanisole (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Laureth-23 (UNII: N72LMW566G)	
Mineral Oil (UNII: T5L8T28FGP)	
Panthenol (UNII: WV9CM0O67Z)	
Propyl Gallate (UNII: 8D4SNN7V92)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Steareth-2 (UNII: V56DFE46J5)	
Steareth-20 (UNII: L0Q8IK9E08)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
Tocopherol (UNII: R0ZB2556P8)	
.Alpha.-Tocopherol (UNII: H4N855PNZ1)	
Water (UNII: 059QF0KO0R)	
Xanthan Gum (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 FINAL	part346	03/01/2014	

Labeler - Dolegencorp,LLC (068331990)

Establishment

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