

**REXALL HEMORRHOIDAL COOLING- phenylephrine hydrochloride and witch hazel gel
Dolgencorp, 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.

REXALL HEMORRHOIDAL COOLING GEL

Active Ingredients

Phenylephrine Hydrochloride 0.25%
Witch Hazel 50%

Purpose

Vasoconstrictor
Astringent

Uses

- temporary 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 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 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 - 26 g Carton Label

REXALL HEMORRHOIDAL COOLING GEL

NET WT .9 OZ (26 g)

Drug Facts

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..... Vasoconstrictor
Witch hazel 50.0%..... Astringent

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Drug Facts (continued)

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Visit us at:
Rexall.com or call
1-866-4-REXALL

PACKAGED FOR
DOLGENCORP, LLC
100 MISSION RIDGE
GOODLETTSVILLE, TN
37072 USA



NET WT .9 OZ (26g)

Since 1903
Rexall

Enriched with Aloe
Hemorrhoidal Cooling Gel

CLEAR, NON-GREASY FORMULA

- Prompt cooling relief from painful burning & itching
- Relieves external discomfort

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REXALL HEMORRHOIDAL COOLING

phenylephrine hydrochloride and witch hazel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-416
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g
WITCH HAZEL (UNII: 10114J0U34) (WITCH HAZEL - UNII:10114J0U34)	WITCH HAZEL	50 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-416-26	26 g in 1 TUBE; Type 0: Not a Combination Product	07/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/12/2017	

Labeler - Dolgencorp, Inc. (068331990)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(55910-416)

Revised: 7/2017

Dolgencorp, Inc.