

REXALL HEMORRHOIDAL COOLING GEL- witch hazel and phenylephrine hydrochloride cream
DOLGENCORP, 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 Cooling Gel
Topical

Drug Facts

Active ingredients	Purposes
Hamamelis virginiana (witch hazel) 50%	Astringent
Phenylephrine hydrochloride 0.25%	Vasoconstrictor

Uses

- temporarily relieves anorectal itching and discomfort associated with hemorrhoids or anorectal disorders
- temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders
- temporarily shrinks hemorrhoidal tissue
- aids in protecting irritated anorectal areas
- temporary relief of burning

Warnings

For external use only.

Do not use this product

- if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

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 recommended daily dosage unless directed by a doctor
- do not put into rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- bleeding occurs

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 gel
- apply externally to affected area up to 4 times daily or after each bowel movement
- **Children under 12 years old:** 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 BROKEN OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, benzophenone-4, disodium EDTA, hydroxyethylcellulose, phenoxy ethenol, propylene glycol, purified water, sodium benzoate, sodium citrate

PRINCIPAL DISPLAY PANEL - 26 g Tube Carton

NDC 55910-332-24

Since 1903
Rexall®

CLEAR, NON-GREASY FORMULA

Hemorrhoidal Cooling Gel

Enriched
with
Aloe

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

NET WT 0.9 OZ (26 g)



REXALL HEMORRHOIDAL COOLING GEL

witch hazel and phenylephrine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-332
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Witch Hazel (UNII: 101I4J0U34) (Witch Hazel - UNII:101I4J0U34)	Witch Hazel	0.5 mg in 1 g
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	0.0025 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Benzophenone (UNII: 701M4TTV9O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Hydroxyethyl Cellulose (280 Mpa.S At 2%) (UNII: 12VCE9HR9E)	

Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Anhydrous Trisodium Citrate (UNII: RS7A450LGA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-332-24	1 in 1 CARTON	03/18/2014	
1		26 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	03/18/2014	

Labeler - DOLGENCORP, LLC (068331990)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(55910-332)

Revised: 12/2022

DOLGENCORP, LLC