REXALL MAXIMUM STRENGTH HEMORRHOIDAL- glycerin, petrolatum, phenylephrine hydrochloride and pramoxine hydrochloride cream
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 Maximum Strength Hemorrhoidal

Active ingredients
Glycerin 14.4%
Petrolatum 15%
Phenylephrine Hydrochloride 0.25%
Pramoxine HCl 1%

Purpose

Protectant
Protectant
Vasoconstrictor
Local anesthetic

Uses
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporary relieves burning
- aid 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 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

aloe barbadensis leaf, 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

REXALL MAXIMUM STRENGTH HEMORRHOIDAL

NET WT 1 OZ (28 g)

REXALL MAXIMUM STRENGTH HEMORRHOIDAL

glycerin, petrolatum, phenylephrine hydrochloride and pramoxine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-406
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	14.4 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	15 g in 100 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	0.25 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55910-406-03	28 g in 1 TUBE; Type 0: Not a Combination Product	06/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/29/2016	

Labeler - Dolgencorp, Inc. (068331990)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(55910-406)

Revised: 7/2016 Dolgencorp, Inc.