REXALL FEMININE MAXIMUM STRENGTH ANTI-ITCH- benzocaine and resorcinol 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 FEMININE MAXIMUM STRENGTH ANTI-ITCH CREAM

Active ingredients

Benzocaine 20%

Resorcinol 3%

Purpose

External Analgesic

External Analgesic

Use

- Temporarily relieves itching

Warnings

For external use only

When using this product avoid contact with eyes

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Also, do not use if you have an unusual or abnormal vaginal discharge except under the supervision of a physician.

Do not apply over large areas of the body.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and older

apply a fingertip amount (approximately 1-inch strip) to Tthe affected area not more than 3 to 4 times daily

children under 12 years

consult a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe vera gel, carbomer, cetyl alcohol, corn oil, disodium EDTA, fragrance, glyceryl stearate,

isopropyl myristate, isopropyl palmitate, lanolin, methyl-4 hydroxybenzoate, mineral oil, PEG-100 stearate, propylene glycol, purified water, stearic acid, stearyl alcohol, triethanolamine, vitamin A, E & D

Principal display panel - 28 g Carton Label

REXALL FEMININE MAXIMUM STRENGTH ANTI-ITCH CREAM

NET WT 1 OZ (28 g)

REXALL FEMININE MAXIMUM STRENGTH ANTI-ITCH

benzocaine and resorcinol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-415
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	3 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CORN OIL (UNII: 8470G57WFM)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TROLAMINE (UNII: 9O3K93S3TK)	
VITAMIN A (UNII: 81G40H8B0T)	
VITAMIN D (UNII: 9VU1KI44GP)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55910-415-03	28 g in 1 TUBE; Type 0: Not a Combination Product	09/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	09/27/2016	

Labeler - Dolgencorp, Inc. (068331990)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(55910-415)

Revised: 9/2016 Dolgencorp, Inc.