

BENZOCAINE AND RESORCINOL - 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.

drug facts

Active ingredients

Purpose

Benzocaine 20%.....External Analgesic

Resorcinol 3%.....External Analgesic

Use temporarily relieves itching

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

Use temporarily relieves itching

Other information - store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F)

Warnings

For external use only.

When using this product avoid contact with the 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

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 the affected area not more than 3 to 4 times daily

children under 12 years

ask a doctor

Inactive Ingredients aloe barbadensis leaf extract, carbomer 940, cetyl alcohol, cholecalciferol, fragrance, glyceryl monostearate, isopropyl myristate, isopropyl palmitate, isopropyl stearate, lanolin alcohol, methylparaben, mineral oil, PEG-100 stearate, propylene glycol, purified water, retinyl palmitate, sodium sulfite, tocopheryl acetate, trisodium HEDTA, trolamine, zeamays (corn) oil



BENZOCAINE AND RESORCINOL

benzocaine and resorcinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10 -185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW2E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL STEARATE (UNII: 43253ZW1MZ)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
VITAMIN A (UNII: 81G40HB0T)	
VITAMIN D (UNII: 9VU1KI44GP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
TRISODIUM HEDTA (UNII: K3E0U7O8KI)	
METHYL PARABEN (UNII: A218C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CORN OIL (UNII: 8470G57WFM)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-185-03	28 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	05/19/2009		

Labeler - Dolgencorp, inc (068331990)

Registrant - Pharma Pac, LLC (140807475)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 7/2011

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