

CALMODROX- menthol, zinc oxide ointment

Geritrex Corp

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.

Calmodrox Ointment

Drug Facts

Active Ingredient	Purpose
Menthol 0.44%	External analgesic First aid antiseptic antipruritic
Zinc Oxide 20.0%	Skin protectant/moisture barrier

Uses

A moisture barrier that prevents and helps heal skin irritation from Urine, diarrhea, perspiration, fistula drainage, feeding tube site leakage, wound drainage (peri-wound skin), minor burns, cuts, scrapes, itching

Directions

Cleanse skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply a thin layer of Calmodrox Ointment to reddened or irritated skin 2-4 times daily or after each incontinent episode or diaper change to promote comfort and long lasting protection

Warnings

FOR EXTERNAL USE ONLY

Not for deep or puncture wounds

Avoid contact with eyes

If condition worsens or does not improve within 7 days, consult a doctor

Inactive Ingredients

Calamine, DMDM Hydantoin, Glycerin, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Phenol, Propylparaben, Propylene Glycol, Purified Water, Sodium Laureth Sulfate, Stearyl Alcohol, Sorbitan Sesquioleate, Sodium bicarbonate and Thymol

KEEP OUT OF REACH OF CHILDREN

In the event of accidental ingestion contact a Poison Control Center right away

Storage

Store at room temperature 15°-30°C (59°-86°F)

Apply a thin layer of Calmodrox Ointment to reddened or irritated skin 2-4 times daily.

NDC# 54162-219-04



CalmodroxTM Ointment

First Aid Ointment

NET WT. 4oz (113 g)

DRUG FACTS:	
Active Ingredient: Menthol 0.44%	Purpose: External analgesic
Zinc Oxide 20.0%	First aid antiseptic/antipruritic Skin protectant/moisture barrier
Uses: A moisture barrier that prevents and helps heal skin irritations from: ♦ Urine ♦ diarrhea ♦ perspiration ♦ fistula drainage ♦ feeding tube site leakage ♦ wound drainage (peri-wound skin) ♦ minor burns ♦ cuts ♦ scrapes ♦ itching	
Warnings: FOR EXTERNAL USE ONLY ♦ Not for deep or puncture wounds ♦ Avoid contact with eyes ♦ If condition worsens or does not improve within 7 days, consult a doctor	
KEEP OUT OF REACH OF CHILDREN. In the event of accidental ingestion contact a Poison Control Center right away.	
Directions: Cleanse skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply a thin layer of Calmodrox Ointment to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection.	
Storage: Store at room temperature 15°-30°C (59°-86°F)	
Inactive Ingredients: calamine, glycerin, lanolin, phenol, sodium bicarbonate, and thymol in a suitable ointment base	

Geritrex Corporation
144 Kingsbridge Road East
Mount Vernon, New York 10550
1-800-736-3437
www.geritrex.com



CALMODROX

menthol, zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-219
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	

PHENOL (UNII: 339NCG44TV)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6HI2BN9U)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-219-04	113 g in 1 TUBE	01/22/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/22/2015	

Labeler - Geritrex Corp (112796248)

Registrant - Geritrex Corp (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex Corp		112796248	manufacture(54162-219)