

**CALADROX- menthol, zinc oxide ointment**  
**Geritrex 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.*

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**Caladrox 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 Caladrox 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 Caladrox Ointment to reddened or irritated skin 2-4 times daily.

NDC# 54162-229-04



# Caladrox<sup>TM</sup> Ointment

First Aid Ointment

NET WT. 4oz (113 g)

### DRUG FACTS:

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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 (periwound 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

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**Directions:**  
Cleanse skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply a thin layer of Caladrox 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 an ointment base

Geritrex  
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Mount Vernon, New York 10550  
**1-800-736-3437**  
www.geritrex.com



## CALADROX

menthol, zinc oxide ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54162-229
<b>Route of Administration</b>	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 CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 g

### Inactive Ingredients

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

<b>PHENOL</b> (UNII: 339NCG44TV)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>THYMOL</b> (UNII: 3J50XA376E)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>WATER</b> (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-229-04	113 g in 1 TUBE; Type 0: Not a Combination Product	09/29/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/29/2015	

**Labeler** - Geritrex LLC (112796248)

**Registrant** - Geritrex LLC (112796248)

**Establishment**

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-229)