LANTISEPTIC CALDAZINC- menthol, zinc oxide ointment
Santus 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.

Lantiseptic CaldaZinc Ointment

Active Ingredient

Menthol 0.45%

Zinc Oxide 18%

Purpose

External analgesic / Anti itch

Skin protectant / Anorectal astringent

Uses

A moisture barrier that prevents and helps heal skin irritation from: •urine • diarrhea • perspiration • fistula damage • 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

Keep out of reach of children

• In case of accidental ingestion contact a physician or poison control center immediately • If condition worsens or does not improve within 7 days, consult a doctor.

Directions

Gently cleanse skin with mild cleanser. Pat dry or allow to air dry. Apply a thin layer of CaldaZinc Ointment to affected area 2-4 times daily or after each incontinent episode or diaper change to promote relief and long-lasting protection.

Other Information

Store at 15-30°C (59-86°F).

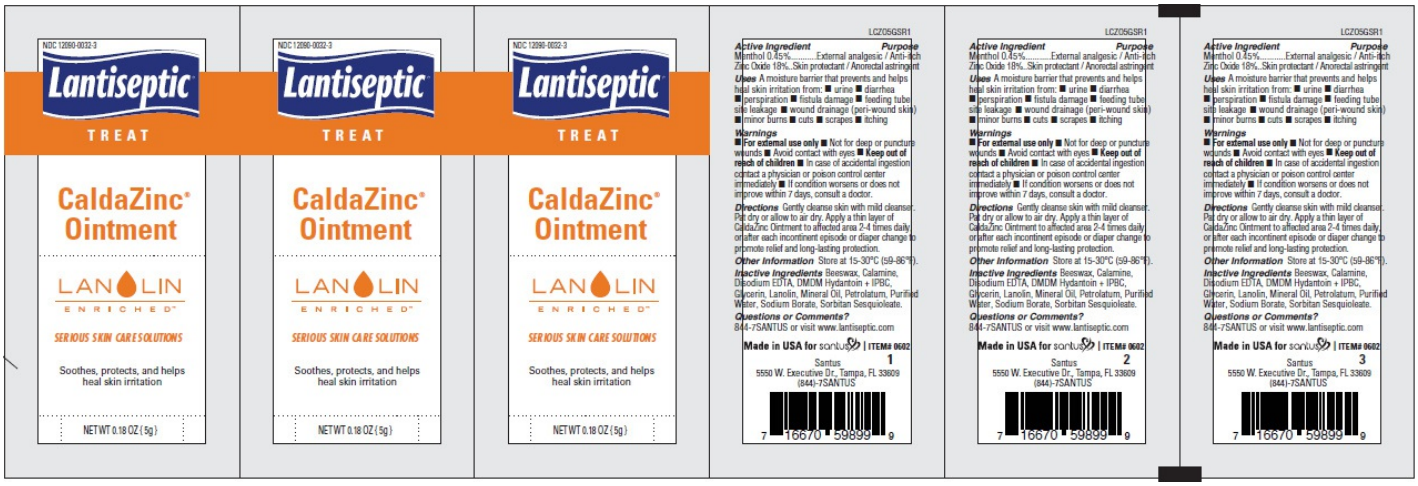
Inactive Ingredients

Beeswax, Calamine, Disodium EDTA, DMDM Hydantoin + IPBC, Glycerin, Lanolin, Mineral Oil, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquioleate.

Questions or Comments?

844-7SANTUS or visit www.lantiseptic.com

Package Labeling:



LANTISEPTIC CALDAZINC

menthol, zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12090-0032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.5 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	180 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
YELLOW WAX (UNII: 2ZA36H0S2V)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:12090-0032-3	5 g in 1 PACKET; Type 0: Not a Combination Product	03/02/2016	
2	NDC:12090-0032-4	113 g in 1 TUBE; Type 0: Not a Combination Product	03/02/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/02/2016	

Labeler - Santus LLC (079868223)

Revised: 1/2017 Santus LLC