

LANOGUARD MULTI-PURPOSE- menthol, calamine, zinc oxide ointment
Summit Industries, 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.

Lanoguard Multi-Purpose Skin Ointment Drug Facts

Active Ingredients

Menthol 0.45%

Calamine 2%

Zinc Oxide 18%

Purpose

External Analgesic, Skin Protectant

Uses

A moisture barrier that prevents and helps protect skin irritations from

- urine
- diarrhea
- perspiration
- fistula drainage
- feeding tube site leakage
- wound drainage
- minor burns
- cuts
- scrapes
- itching

Warnings

- **For external use only.**
- **When using this product**
- do not get into eyes.

Stop use and ask doctor if :

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

When practical, gently cleanse and dry area.

- **Adults:** Apply externally to affected area up to 6 times daily or after each incontinent episode or diaper change.
- **Children under 12 years:** Consult a doctor.

Other Information

Store at 15-30°C (59-86°F)

Inactive Ingredients:

Beeswax, Disodium EDTA, Glycerin, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Purified Water, Sodium Borate, Sorbitan Sesquioleate

Questions or Comments?

1-800-241-6996

SUMMIT INDUSTRIES, INC

PO Box 7329, Marietta, GA 30065

www.lantiseptic.com

Item # 0610

Image of representative container artwork

LanoguardMPSO5goz.jpg

NDC 12090-0061-0



Multi-Purpose Skin Ointment

Protect and Help Treat

Temporarily protects irritated skin due to incontinence, diaper rash and chafing.
Temporarily relieves itching.

External Analgesic
Skin Protectant

NET WT 5g {0.18 oz}

Drug Facts

Active Ingredient	Purpose
Menthol 0.45%.....	External Analgesic
Calamine 2%	Skin Protectant
Zinc Oxide 18%	Skin Protectant

Uses A moisture barrier that prevents and helps protect skin irritations from ■ urine ■ diarrhea ■ perspiration ■ fistula drainage ■ feeding tube site leakage ■ wound drainage ■ minor burns ■ cuts ■ scrapes ■ itching.

Warnings ■ For external use only. ■ When using this product ■ do not get into eyes. ■ Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions When practical, gently cleanse and dry area. ■ Adults: Apply externally to affected area up to 6 times daily or after each incontinent episode or diaper change. ■ Children under 12 years: Consult a doctor.

Other information
Store at 15°C - 30°C (59°F - 86°F).

Inactive ingredients Beeswax, Disodium EDTA, Glycerin, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Purified Water, Sodium Borate, Sorbitan Sesquioleate.

Questions or Comments? 1-800-241-6996

SUMMIT INDUSTRIES, INC.
PO Box 7329
Marietta, GA 30065
www.lantiseptic.com
ITEM # 0610



0 0005 04 1

LANOGUARD MULTI-PURPOSE

menthol, calamine, zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12090-0061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	4.5 mg in 1 g
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	20 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	180 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12090-0061-0	5 g in 1 PACKET		
2	NDC:12090-0061-5	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/21/2013	

Labeler - Summit Industries, Inc. (003279189)

Establishment

Name	Address	ID/FEI	Business Operations
Summit Industries, Inc.		003279189	manufacture(12090-0061)

Revised: 3/2013

Summit Industries, Inc.