LANOGUARD DRY SKIN THERAPY- lanolin cream 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.

Lano Guard Dry Skin Therapy Therapeutic Cream Drug Facts

Active Ingredient

Lanolin USP 37%

Purpose

Skin Protectant

Uses

- Helps protect ulcer prone skin.
- For treatment of cracked skin, minor burns or irritation.
- Helps prevent chafing and dryness.

Warnings

- For external use only.
- Avoid contact with eyes.
- Do not apply to deep or puncture wounds.
- If condition worsens, or does not improve within 7 days, consult a doctor.
- If swallowed, get medical help or contact a Poison Control Center right away.
- Keep out of reach of children.

Directions

- Gently cleanse and dry area.
- Massage liberally into affected area as needed.
- Cover treated feet.

Other Information

Store at 20-25°C (68-77°F)

Inactive Ingredients:

Beeswax (yellow wax), Fragrance, HEEDTA, Lanolin Alcohol, Mineral Oil, Oxyquinoline, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquioleate

Questions Comments?

1-800-241-6996 or www.lantiseptic.com

SUMMIT INDUSTRIES, INC

Lantiseptic Division

Image of representative artwork

LanoGuardDrySkinfouroz.jpg





Therapeutic Cream

Formulated to moisturize and protect severely dry, cracked, chafed and ulcer prone skin.

SKIN PROTECTANT

NET WT 4 OZ { 113g }

NDC#: 12090-0042-5 | TEM# 0425

Drug Facts

Active ingredient

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Summit Industries, Inc. Lantiseptic Division PO BOX 7329 Marietta, GA 30065



LANOGUARD DRY SKIN THERAPY

lanolin cream

Product Information

Route of Administration

Product Type HUMAN OTC DRUG

TOPICAL

Item Code (Source)

NDC:12090-0042

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)

Inactive Ingredients

Ingredient Name Strength

YELLOW WAX (UNII: 2ZA36H0S2V)

HYDRO XYETHYLETHYLENEDIAMINETRIACETIC ACID (UNII: R79 J9 1U341)

LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MINERAL OIL (UNII: T5L8T28FGP)	
OXYQUINOLINE (UNII: 5UTX5635HP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:12090-0042-5	113 g in 1 TUBE			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part347	12/30/2009					

Labeler - Summit Industries, Inc. (003279189)

Establishment						
Name	Address	ID/FEI	Business Operations			
Summit Industries, Inc.		003279189	manufacture(12090-0042)			

Revised: 3/2013 Summit Industries, Inc.