LANTISEPTIC 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.

Lantis eptic 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

If you have questions or comments, call

800-241-6996 or visit

www.Lantiseptic.com

SUMMIT INDUSTRIES, INC

Lantiseptic Division

Image of representative container

TC_113.jpg



LANTISEPTIC DRY SKIN THERAPY

lanolin cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:12090-0016
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LANOLIN (LANOLIN)	LANOLIN	370 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
YELLOW WAX		
HYDRO XYETHYLETHYLENEDIAMINETRIACETIC ACID		

LANOLIN ALCOHOLS	
MINERAL OIL	
OXYQUINOLINE	
PETROLATUM	
WATER	
SODIUM BORATE	
SORBITAN SESQUIO LEATE	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12090-0016-2	14.2 g in 1 PACKET		
2	NDC:12090-0016-1	113 g in 1 TUBE		
3	NDC:12090-0016-3	227 g in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part347	12/30/2009		

Labeler - Summit Industries, Inc. (003279189)

Registrant - Summit Industries, Inc. (003279189)

Establishment				
Name	Address	ID/FEI	Business Operations	
Summit Industries, Inc.		003279189	manufacture(12090-0016)	

Revised: 1/2013 Summit Industries, Inc.