LANTISEPTIC DRY SKIN THERAPY- lanolin cream
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 Dry Skin Therapy Cream

Drug Facts

Active Ingredient

Lanolin USP 30%

Purpose

Skin Protectant

Uses

• Helps protect ulcer prone skin. • For treatment of cracked skin, minor burns or irritations. • 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 15-30°C (59-86°F)

Inactive Ingredients

Beeswax (Yellow Wax), Disodium EDTA, DMDM Hydantoin + IPBC, Lanolin Alcohol, Mineral Oil, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquioleate.

Questions or Comments?

844-7SANTUS or visit www.lantiseptic.com

Package Labeling:

LANTISEPTIC DRY SKIN THERAPY

lanolin cream

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	300 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
YELLOW WAX (UNII: 2ZA36H0S2V)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
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:12090-0016-2	14.2 g in 1 PACKET; Type 0: Not a Combination Product	03/02/2016	
2	NDC:12090-0016-1	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	part347	03/02/2016	

Labeler - Santus LLC (079868223)

Revised: 1/2017 Santus LLC