LANTISEPTIC ORIGINAL SKIN PROTECTANT- 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 Original Skin Protectant Cream

Active Ingredient

Lanolin USP 50%

Purpose

Skin Protectant

Uses

• Helps prevent and treat skin irritations. • Protects chafed skin or minor skin irritations due to incontinence •Helps seal out wetness.

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. • Apply liberally to affected area as needed.

Other Information

Store at 15-30°C (59-86°F)

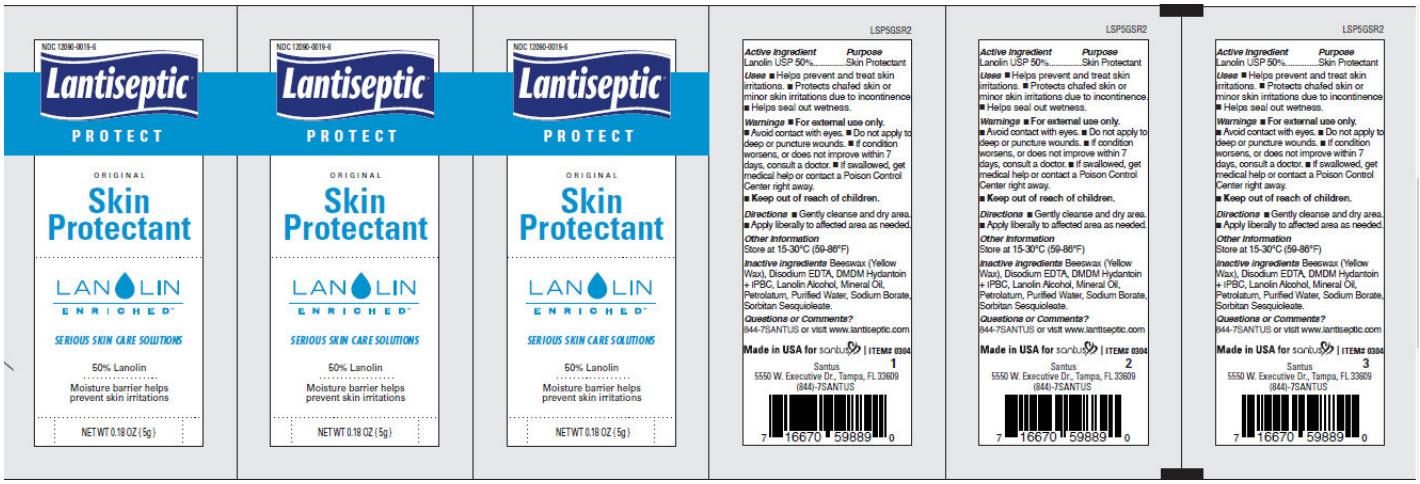
Inactive Ingredients

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 ORIGINAL SKIN PROTECTANT

lanolin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12090-0019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	500 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:12090-0019-6	5 g in 1 PACKET; Type 0: Not a Combination Product	03/03/2016	
2	NDC:12090-0019-1	14.2 g in 1 PACKET; Type 0: Not a Combination Product	03/03/2016	
3	NDC:12090-0019-3	113 g in 1 TUBE; Type 0: Not a Combination Product	03/03/2016	
4	NDC:12090-0019-4	130 g in 1 JAR; Type 0: Not a Combination Product	03/03/2016	
5	NDC:12090-0019-7	1 in 1 CARTON	03/03/2016	
5		340 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/03/2016	

Labeler - Santus LLC (079868223)

Revised: 1/2017 Santus LLC