

LANOLIN- lanolin ointment
Sion Biotext Medical Ltd

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.

Lantisepton Ointment

Active ingredient	Purpose
Lanolin USP 50%	Skin Protectant

Uses:

- Helps prevent and treat diaper dermatitis
- Protects chafed skin or minor skin irritations due to incontinence and helps seal out wetness

For External Use Only

Indications and Usage

- 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

Directions:

- Gently cleanse and dry area
- Apply liberally to affected area as needed

Inactive Ingredient

Inactive Ingredients: Beeswax, Fragrance, HEEDTA, Lanolin alcohol, Mineral Oil, Oxyquinoline, Petrolatum, Purified water, Sodium borate, Sesquioleate

Keep Out Of Reach Of Children

Keep Out Of Reach Of Children

Principal Display Panel

Sion Biotext Medical Ltd

LANTISEPTON OINTMENT

SKIN BARRIER

FOR INCONTINENCE DIAPER DERMATITIS, CHAFED OR ULCER PRONE SKIN

NET WT. 4 oz (113.6 g)

Drug Facts (continued)	
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. ▼	

Drug Facts (continued)	
Other Information: • Store at room temperature 20°-25°C (68°-77°F)	
Tamper Evident: • Do not use if packet is broken or damaged.	
Inactive Ingredients Beeswax (Yellow Wax), Fragrance, HEEDTA, Lanolin Alcohol, Mineral oil, Oxyquinoline, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquioleate	

Sion Biotext Medical Ltd.	LANTISEPTON OINTMENT
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Lanolin USP 50%	Skin Protectant
Uses	
• helps prevent and treat diaper dermatitis. • Protects chafed skin or minor skin irritations due to incontinence and helps seal out wetness. ▼	

Manufactured by:
Sion Biotext Medical Ltd.
Hagoshrim, 12225, ISRAEL.
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Tel: 972-4-6956201, Fax: 972-4-6956202
Made in Israel
NDC #68786-232-04

LANOLIN

lanolin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68786-232
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII: 7EV65EAW6H)	LANOLIN	50 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MINERAL OIL (UNII: T5L8T28FGP)	
OXYQUINOLINE (UNII: 5UTX5635HP)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68786-232-01	2 in 1 CASE	07/09/2012	
1		144 in 1 BOX		
1		5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:68786-232-02	4 in 1 CASE	07/09/2012	
2		36 in 1 BOX		
2		15 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:68786-232-03	36 in 1 CASE	07/09/2012	
3		71 g in 1 JAR; Type 0: Not a Combination Product		
4	NDC:68786-232-04	24 in 1 CASE	07/09/2012	
4		114 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:68786-232-05	24 in 1 CASE	07/09/2012	
5		71 g in 1 JAR; Type 0: Not a Combination Product		
6	NDC:68786-232-06	12 in 1 CASE	07/09/2012	
6		396.8 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	07/09/2012	

Labeler - Sion Biotext Medical Ltd (532775194)

Registrant - Sion Biotext Medical Ltd (532775194)**Establishment**

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical Ltd		532775194	manufacture(68786-232)

Revised: 1/2022

Sion Biotext Medical Ltd