

**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**

<b>Active ingredient</b>	<b>Purpose</b>
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 Sesquileate

**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**

**Active Ingredient**

Lanolin USP 50%

**Purpose**

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.  
E-mail: sbmedical@sb-medical.com  
Tel: 972-4-6956201, Fax: 972-4-6956202

Made in Israel  
NDC #68786-232-04

**LANOLIN**

lanolin ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68786-232
<b>Route of Administration</b>	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)	

<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>OXYQUINOLINE</b> (UNII: 5UTX5635HP)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	
<b>WATER</b> (UNII: 059QF0K00R)	

### 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)

### Establishment

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

Revised: 6/2019

Sion Biotext Medical Ltd