

**LANTISEPTIC BY DERMARITE ORIGINAL SKIN PROTECTANT- lanolin cream**  
**Dermarite Industries 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.*

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**Lantisepic by Dermarite Moisture Shield Original Skin Protectant**

**Drug Facts**

***Active Ingredient***

Lanolin USP 50%

***Purpose***

Skin Protectant

***Uses***

- Helps relieve and prevent rashes and irritation due to wetness from incontinence.
- Protects chafed skin due to irritation and helps seal out wetness.

***Warnings***

For external use only.

Avoid contact with eyes.

In case of contact, flush thoroughly with water.

Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.

Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.

***Directions***

- Cleanse and remove any urine or fecal matter from area; pat dry.
- Apply generously to affected area as needed, especially after incontinence episodes.
- Repeat after each incontinent episode or as needed.

***Other Information***

- Store at room temperature (59-86°F)
- You may report a serious adverse event to DermaRite Industries, PO box 7209, North Bergen, NJ 07047

***Inactive Ingredients***

Cera Alba, DMDM Hydantoin, Disodium EDTA, Lanolin Alcohol, Mineral Oil, Petrolatum, Sodium borate, Sorbitan Sesquioleate, Water

**Questions or Comments?**

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

Package Label Principal Display Panel

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">NDC 61924-304-04</p>  <p style="text-align: center;"><b>Moisture Shield</b></p> <p style="text-align: center;">ORIGINAL <b>SKIN PROTECTANT</b></p> <p style="text-align: center;">         50% Lanolin        .....        Moisture barrier helps        prevent skin irritations     </p> <p><b>REORDER #LS0308</b>      Net Wt. 113 g (4 oz.)</p>	<div style="text-align: right; writing-mode: vertical-rl; transform: rotate(180deg);">Patient Name</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center;"><b>Drug Facts</b></td> </tr> <tr> <td style="width: 50%;"><b>Active ingredient</b></td> <td style="width: 50%;"><b>Purpose</b></td> </tr> <tr> <td>Lanolin USP 50% .....</td> <td>Skin protectant</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>■ Helps relieve and prevent rashes and irritation due to wetness from incontinence.</li> <li>■ Protects chafed skin due to irritation and helps seal out wetness.</li> </ul> </td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2"><b>For external use only.</b></td> </tr> <tr> <td colspan="2"><b>Avoid contact with eyes.</b> In case of contact, flush thoroughly with water.</td> </tr> <tr> <td colspan="2"><b>Stop use and ask a doctor if</b> ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days.</td> </tr> <tr> <td colspan="2"><b>Keep out of reach of children.</b> In case of accidental ingestion contact a physician or Poison Control Center right away.</td> </tr> <tr> <td colspan="2"><b>Directions</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>■ Cleanse and remove any urine or fecal matter from area; pat dry.</li> <li>■ Apply generously to affected area as needed, especially after incontinence episodes.</li> <li>■ Repeat after each incontinent episode or as needed.</li> </ul> </td> </tr> <tr> <td colspan="2"><b>Other information</b> ■ Store at room temperature (59°-86°F). ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.</td> </tr> <tr> <td><b>Inactive ingredients</b></td> <td>Cera Alba, DMDM Hydantoin, Disodium EDTA, Lanolin Alcohol, Mineral Oil, Petrolatum, Sodium Borate, Sorbitan Sesquioleate, Water</td> </tr> <tr> <td colspan="2"><b>Questions?</b> Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.</td> </tr> </table> <div style="text-align: right; writing-mode: vertical-rl; transform: rotate(180deg);">Room #</div> <div style="text-align: center; margin-top: 20px;">         7 14 196 03084 9     </div> <p style="text-align: center; margin-top: 20px;"><b>DermaRite</b></p> <p style="text-align: center;">DermaRite Industries LLC • 7777 West Side Avenue North Bergen, NJ 07047 • www.dermarite.com</p> <p style="text-align: right; margin-top: 20px;"><b>MADE IN THE USA</b> 100238</p>	<b>Drug Facts</b>		<b>Active ingredient</b>	<b>Purpose</b>	Lanolin USP 50% .....	Skin protectant	<b>Uses</b>		<ul style="list-style-type: none"> <li>■ Helps relieve and prevent rashes and irritation due to wetness from incontinence.</li> <li>■ Protects chafed skin due to irritation and helps seal out wetness.</li> </ul>		<b>Warnings</b>		<b>For external use only.</b>		<b>Avoid contact with eyes.</b> In case of contact, flush thoroughly with water.		<b>Stop use and ask a doctor if</b> ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days.		<b>Keep out of reach of children.</b> In case of accidental ingestion contact a physician or Poison Control Center right away.		<b>Directions</b>		<ul style="list-style-type: none"> <li>■ Cleanse and remove any urine or fecal matter from area; pat dry.</li> <li>■ Apply generously to affected area as needed, especially after incontinence episodes.</li> <li>■ Repeat after each incontinent episode or as needed.</li> </ul>		<b>Other information</b> ■ Store at room temperature (59°-86°F). ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.		<b>Inactive ingredients</b>	Cera Alba, DMDM Hydantoin, Disodium EDTA, Lanolin Alcohol, Mineral Oil, Petrolatum, Sodium Borate, Sorbitan Sesquioleate, Water	<b>Questions?</b> Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.	
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**LANTISEPTIC BY DERMARITE ORIGINAL SKIN PROTECTANT**

lanolin cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61924-304
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	500 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WHITE WAX (UNII: 7G1J5DA97F)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-304-05	5 g in 1 PACKET; Type 0: Not a Combination Product	12/25/2018	
2	NDC:61924-304-14	14.2 g in 1 PACKET; Type 0: Not a Combination Product	12/25/2018	
3	NDC:61924-304-04	113 g in 1 TUBE; Type 0: Not a Combination Product	12/25/2018	
4	NDC:61924-304-45	130 g in 1 JAR; Type 0: Not a Combination Product	12/25/2018	
5	NDC:61924-304-12	340 g in 1 JAR; Type 0: Not a Combination Product	12/25/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/25/2018	

**Labeler** - Dermarite Industries LLC (883925562)