

## **PRIMAGUARD DAILY CARE SKIN PROTECTANT- lanolin ointment**

### **First Choice Medical Supply**

*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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### **PrimaGuard Daily Care Skin Protectant Drug Facts**

#### **Active Ingredient**

Lanolin USP 30%

#### **Purpose**

Skin Protectant

#### **Uses**

- Helps prevent and treat skin irritations.
- Protects chafed skin or minor skin irritations due to incontinence and 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 20-25°C (68-77°F)

#### **Inactive ingredients:**

Beeswax (yellow wax), Disodium EDTA, Fragrance, Lanolin Alcohol, Mineral Oil, Oxyquinoline, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquioleate

Questions or comments?

Call 800-809-4556

or visit [www.fcms](http://www.fcms)

First Choice Medical Supply

127 Interstate Dr.

Richland, MS 39218

# Images of representative container artwork

PrimaGuardProtectTubeLabel.jpg

REORDER# 33434



## DAILY CARE Skin Protectant

**Recommended for Daily Use to:**

- Prevent Incontinence Skin Irritations
- Moisturize Dry, Cracked Skin
- Prevent Skin Tears & Cracks
- Prevent Chafing & Rashes

**PROTECT**



NET WT 4 OZ (113g)

Patient Name: \_\_\_\_\_

Room#: \_\_\_\_\_

**Drug Facts**

Active Ingredient	Purpose
Lanolin USP 30% .....	Skin Protectant

**USES:** Helps Prevent and treat diaper dermatitis, Protects chafed skin or minor skin irritations due to incontinence and helps seal out wetness.

**WARNINGS: FOR EXTERNAL USE ONLY.**

- Avoid contact with eyes.
- Do not apply to deep or puncture wounds.
- If conditions 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 20-25° C (68-77° F)

**INACTIVE INGREDIENTS:** Beeswax (yellow wax), Disodium EDTA, Fragrance, Lanolin Alcohol, Mineral Oil, Oxyquinoline, Petrolatum, Purified Water, Sodium Borate, Sorbitan Sesquileate.



FCMS33434



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## PRIMAGUARD DAILY CARE SKIN PROTECTANT

lanolin ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75904-3343
<b>Route of Administration</b>	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)	
OXYQUINOLINE (UNII: 5UTX5635HP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	

SODIUM BORATE (UNII: 91MBZ8H3QO)

SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75904-3343-4	5 g in 1 POUCH		
2	NDC:75904-3343-5	113 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/28/2011	

**Labeler** - First Choice Medical Supply (117734405)

**Registrant** - Summit Industries, Inc. (003279189)

### Establishment

Name	Address	ID/FEI	Business Operations
Summit Industries, Inc.		003279189	manufacture(75904-3343)

Revised: 3/2013

First Choice Medical Supply