

## **EIGHT HOUR CREAM SKIN PROTECTANT - petrolatum lotion**

**Elizabeth Arden, Inc**

*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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**BC0105**

### **DESCRIPTION**

(On Box) Uses: Treats symptoms of: chapping, peeling or flaking due to minor burns, sunburn, windburn, scrapes, abrasions, cracked lips.

(On Tube) Soothes minor skin irritations. Also for symptoms of chapping, peeling or flaking due to minor burns, sunburn, windburn, scrapes, abrasions or cracked lips.

### **INDICATIONS AND USAGE**

To Use: Apply liberally as often as necessary.

### **WARNINGS**

(On Box) Warnings: For external use only. When using this product: Avoid contact with eyes. Do not apply over puncture wounds, infections, or lacerations. Stop using and ask a doctor if: symptoms persist more than 7 days.

(On Tube) Warning: For external use only. Avoid contact with eyes. Discontinue use if symptoms persist more than 7 days and consult a physician. Not to be applied over puncture wounds, infections, or lacerations.

### **OTC - ACTIVE INGREDIENT**

Active Ingredient: Petrolatum 56.8%.

### **INACTIVE INGREDIENT**

Inactive Ingredients: Lanolin, Mineral Oil, Tocopherol, BHT, Salicylic Acid, Ricinus Communis (Castor) Seed Oil, Vegetable Oil, Zea Mays (Corn) Oil, Fragrance, Citral, Citronellol, Geraniol, Limonene, Linalool, Propylparaben, Iron Oxides.

### **DOSAGE & ADMINISTRATION**

Apply liberally.

### **OTC - KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children.

### **OTC - PURPOSE**

Skin protectant.

**OTC - WHEN USING**

Avoid contact with eyes.

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**Drug Facts**

| <b>Active Ingredient</b> | <b>Purpose</b>  |
|--------------------------|-----------------|
| Petrolatum 56.8%.....    | Skin Protectant |

**Uses** Treats symptoms of:  
■ chapping ■ peeling or flaking due to minor burns ■ sunburn ■ windburn ■ scrapes ■ abrasions ■ cracked lips

**Warnings**  
■ For external use only

**When using this product**  
■ Avoid contact with eyes  
■ Do not apply over puncture wounds, infections or lacerations

**Stop using and ask a doctor if**  
■ Symptoms persist more than 7 days

**Directions**  
■ Apply liberally as often as necessary

**Inactive Ingredients**  
Lanolin, Mineral Oil, Tocopherol, BHT, Salicylic Acid, Ricinus Communis (Castor) Seed Oil, Vegetable Oil, Zea Mays (Corn) Oil, Fragrance, Citral, Citronellol, Geraniol, Limonene, Linalool, Propylparaben, Iron Oxides.

Distributed in U.S.A. by  
©Elizabeth Arden, Inc.  
New York, NY 10003

Eight Hour  
Cream  
Skin Protectant

Made in U.S.A.  
ElizabethArden.com  
No. 4252000



This carton is recyclable.

NET WT. 1.7 OZ.  
50 g

Elizabeth Arden



Soothes minor skin irritations. Also for symptoms of chapping, peeling or flaking due to minor burns, sunburn, windburn, scrapes, abrasions or cracked lips.

To use: Apply liberally as often as necessary.

**Warning:** For external use only. Avoid contact with the eyes. Discontinue use if symptoms persist for more than 7 days and consult a physician. Not to be applied over puncture wounds, infections or lacerations.

ACTIVE INGREDIENT:  
PETROLATUM 56.8%

NET WT. 1.7 OZ. 50 g

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**OTHER**

Please recycle

**Eight Hour  
Cream  
Skin Protectant**

## EIGHT HOUR CREAM SKIN PROTECTANT

petrolatum lotion

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:67938-0105 |
| Route of Administration | TOPICAL        |                    |                |

Active Ingredient/Active Moiety

| Ingredient Name  |  | Basis of Strength    | Strength             |                    |
|--|--|----------------------|----------------------|--------------------|
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) |  | PETROLATUM           | 28.4 g in 50 g       |                    |
| <b>Inactive Ingredients</b>                                  |  |                      |                      |                    |
| Ingredient Name  |  | Strength             |                      |                    |
| LANOLIN (UNII: 7EV65EAW6H)                                   |  |                      |                      |                    |
| MINERAL OIL (UNII: T5L8T28FGP)                               |  |                      |                      |                    |
| SALICYLIC ACID (UNII: O414PZ4LPZ)                            |  |                      |                      |                    |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                             |  |                      |                      |                    |
| CASTOR OIL (UNII: D5340Y2I9G)                                |  |                      |                      |                    |
| CORN OIL (UNII: 8470G57WFM)                                  |  |                      |                      |                    |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)                          |  |                      |                      |                    |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)                  |  |                      |                      |                    |
| <b>Packaging</b>   |  |                      |                      |                    |
| #  | Item Code                                | Package Description  | Marketing Start Date | Marketing End Date |
| 1  | NDC:67938-0105-1                         | 1 in 1 BOX           |                      |                    |
| 1  | NDC:67938-0105-2                         | 50 g in 1 TUBE       |                      |                    |
| 2  | NDC:67938-0105-3                         | 1 in 1 BOX           |                      |                    |
| 2  | NDC:67938-0105-4                         | 15 g in 1 TUBE       |                      |                    |
| 3  | NDC:67938-0105-5                         | 1 in 1 BOX           |                      |                    |
| 3  | NDC:67938-0105-6                         | 30 g in 1 TUBE       |                      |                    |
| <b>Marketing Information</b>                                 |  |                      |                      |                    |
| Marketing Category   | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date   |                    |
| OTC monograph final  | part347                                  | 11/03/2009           |                      |                    |

**Labeler** - Elizabeth Arden, Inc (849222187)

Revised: 1/2011

Elizabeth Arden, Inc