

## **EIGHT HOUR SKIN FRAGRANCE FREE- petrolatum cream REVLON**

*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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## **ELIZABETH ARDEN EIGHT HOUR CREAM SKIN PROTECTANT FRAGRANCE FREE**

### **ACTIVE INGREDIENT**

PETROLATUM 56.8%

### **INACTIVE INGREDIENTS**

LANOLIN, MINERAL OIL/PARAFFINUM LIQUIDUM/HUILE MINÉRALE, ACACIA DECURRENS EXTRACT, DIPTERYX ODORATA BEAN EXTRACT, VANILLIN, TOCOPHEROL, TOCOPHERYL ACETATE, BHT, SALICYLIC ACID, RICINUS COMMUNIS (CASTOR) SEED OIL, VEGETABLE OIL/OLUS/HUILE VÉGÉTALE, ZEA MAYS (CORN) OIL, BENZYL ALCOHOL, IRON OXIDES

### **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

**CARTON ART**

 <p>NET WT. 1.7 OZ. 50 g</p>	<p>Elizabeth Arden NEW YORK</p>	<p>Elizabeth Arden NEW YORK</p> <p>FRAGRANCE FREE</p> <p><b>Eight Hour Cream</b> Skin Protectant</p> <p>NET WT. 1.7 OZ. 50 g</p>	<p>This fragrance free version of the legendary skincare classic works wonders to moisturize and protect anytime, anyway you choose. Shape brows, revitalize shine, soothe dry hands and smooth cuticles and nails.</p> <p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Petrolatum 56.8%</td> <td>Skin Protectant</td> </tr> </tbody> </table> <p><b>Uses</b> Treats symptoms of:  <input type="checkbox"/> chapping <input type="checkbox"/> peeling or flaking due to minor burns <input type="checkbox"/> sunburn <input type="checkbox"/> windburn <input type="checkbox"/> scrapes <input type="checkbox"/> abrasions <input type="checkbox"/> cracked lips</p> <p><b>Warnings</b>  <input type="checkbox"/> For external use only</p> <p><b>When using this product</b>  <input type="checkbox"/> Avoid contact with eyes  <input type="checkbox"/> Do not apply over puncture wounds, infections or lacerations</p> <p><b>Stop using and ask a doctor if</b>  <input type="checkbox"/> Symptoms persist more than 7 days</p> <p><b>Directions</b>  <input type="checkbox"/> Apply liberally as often as necessary</p> <p><b>Inactive Ingredients</b>          LANOLIN, MINERAL OIL / PARAFFINUM LIQUIDUM / HUILE MINERALE, ACACIA DECURRENS EXTRACT, DIPTERYX ODORATA BEAN EXTRACT, VANILLIN, TOCOPHEROL, TOCOPHERYL ACETATE, BHT, SALICYLIC ACID, RICINUS COMMUNIS (CASTOR) SEED OIL, VEGETABLE OIL / OLUS / HUILE VEGETALE, ZEA MAYS (CORN) OIL, BENZYL ALCOHOL, IRON OXIDES.</p> <p>Distributed in U.S.A. by          ©Elizabeth Arden, Inc.          New York, NY 10003  <a href="http://ElizabethArden.com">ElizabethArden.com</a></p> <p>Made in U.S.A.          No. EIGN00065</p> <p>This carton is recyclable. </p>	Active Ingredient	Purpose	Petrolatum 56.8%	Skin Protectant
Active Ingredient	Purpose						
Petrolatum 56.8%	Skin Protectant						

**EIGHT HOUR SKIN FRAGRANCE FREE**

petrolatum cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10967-673
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)			PETROLATUM	56.8 mg in 1 g
Inactive Ingredients				
Ingredient Name				Strength
MINERAL OIL (UNII: T5L8T28FGP)				
ACACIA DECURRENS WHOLE (UNII: 8KZ75S2VSK)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
SALICYLIC ACID (UNII: O414PZ4LPZ)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
CORN OIL (UNII: 8470G57WFM)				
DIPTERYX ODORATA SEED (UNII: D43A5L1U6L)				
VANILLIN (UNII: CHI530446X)				
CASTOR OIL (UNII: D5340Y2I9G)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
LANOLIN (UNII: 7EV65EAW6H)				
TOCOPHEROL (UNII: R0ZB2556P8)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-673-17	50 g in 1 TUBE; Type 0: Not a Combination Product	04/15/2013	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	04/15/2013		

**Labeler** - REVLON (788820165)

**Registrant** - REVLON (788820165)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Essence, LLC dba Voyant Beauty		032565959	manufacture(10967-673)

### Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab. INC.		080987545	manufacture(10967-673)

