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.

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, Rincinus 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.

Avoid contact with eyes.

Elizabeth Arden



Drug Facts

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

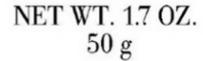
Directions

Apply liberally as often as necessary

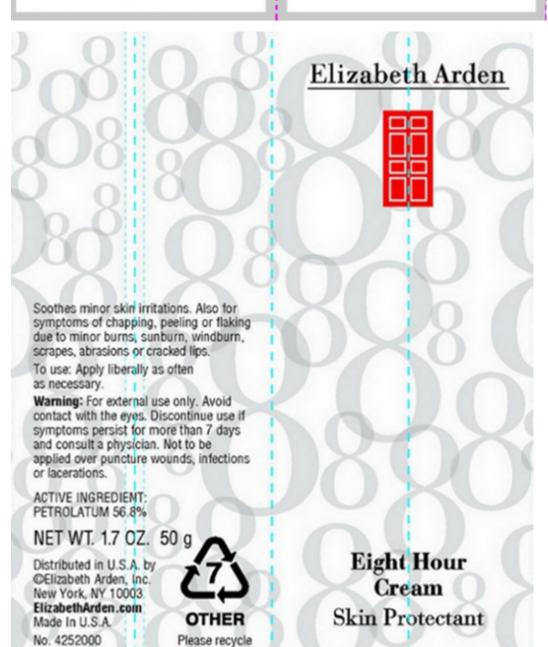
Inactive Ingredients

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







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

Inactive Ingredients				
Ingredient Name	Strength			
LANOLIN (UNII: 7EV65EAW6H)				
MINERAL OIL (UNII: T5L8T28FGP)				
SALICYLIC ACID (UNII: O414PZ4LPZ)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
CASTOR OIL (UNII: D5340 Y2I9G)				
CORN OIL (UNII: 8470 G57WFM)				
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)				
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)				

P	Packaging						
#	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					

Marketing Information					
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