

EIGHT HOUR CREAM TARGETED SUN DEFENSE SPF 50- homosalate stick

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.

BC1130

DESCRIPTION

Target over-exposed areas such as lips, nose, earlobes, even scars to shield from the burning and aging effects of UVA and UVB rays. Eight Hour Cream hydrating benefits sooth and smooth for up to 8 hours.

Oil-free. Water-resistant. PABA-free. Non-acnegenic. Perspiration-resistant. Suitable for all skin types. Ophthalmologist, clinically and dermatologist tested.

Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection. Retains SPF after 40 minutes of swimming or perspiring.

Sun Alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risk of skin cancer and other harmful effects of the sun.

INDICATIONS AND USAGE

Directions: Apply liberally and evenly to targeted areas 30 minutes before sun exposure and as needed. Reapply after 40 minutes of swimming or perspiring, and after towel drying. Otherwise, reapply at least every 2 hours. Children under 6 months of age: ask a doctor.

WARNINGS

Warnings: For external use only. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of reach of children. If swallowed, get medical help or contact a poison controll center right away.

OTC - ACTIVE INGREDIENT

Active Ingredients: Homosalate 7.5% w/w, Octinoxate 7.5% w/w, Octocrylene 5.0% w/w, Oxybenzone 4.0% w/w, Avobenzone 2.0% w/w.

INACTIVE INGREDIENT

Other Ingredients: Octyldodecyl Myristate, Polyethylene, Phenyl Trimethicone, Tocopheryl Acetate, Caprylyl Glycol, Parfum/Fragrance, Citral, Citronellol, Geraniol, Limonene, Linalool, Phenoxyethanol.

DOSAGE & ADMINISTRATION

Apply evenly and liberally to targeted areas.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

Helps prevent sunburn. Higher SPF gives more sun protection.

OTC - WHEN USING

Keep out of eyes.

<p>Target over-exposed areas such as lips, nose, earlobes, even scars to shield from the burning and aging effects of UVA and UVB rays. Eight Hour Cream hydrating benefits soothe and smooth for up to 8 hours.</p> <p>Oil-free Water-resistant PABA-free Non-acneogenic Perspiration-resistant Suitable for all skin types Ophthalmologist, clinically and dermatologist tested</p> <p>Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection. Retains SPF after 40 minutes of swimming or perspiring.</p> <p>WARNINGS: FOR EXTERNAL USE ONLY. WHEN USING THIS PRODUCT, KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS AND LASTS. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.</p> <p>Sun alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risk of skin cancer and other harmful effects of the sun.</p> <p>Directions: Apply liberally and evenly to targeted areas 30 minutes before sun exposure and as needed. Reapply after 40 minutes of swimming or perspiring, and after towel drying. Otherwise reapply at least every 2 hours. Children under 6 months of age: ask a doctor.</p>	<p>ACTIVE INGREDIENTS: HOMOSALATE 7.5 % W/W OCTINOXATE 7.5 % W/W OCTOCRYLENE 5.0 % W/W OXYBENZONE 4.0 % W/W AVOBENZONE 2.0 % W/W</p> <p>OTHER INGREDIENTS: OCTYLDODECYL MYRISTATE, POLYETHYLENE, PHENYL TRIMETHICONE, TOCOPHERYL ACETATE, CAPRYLYL GLYCOL, PARFUM/FRAGRANCE, CITRAL, CITRONELLOL, GERANIOL, LIMONENE, LINALOOL, PHENOXYETHANOL.</p> <p>Distributed in U.S.A. by ©Elizabeth Arden, Inc. New York, NY 10003 ElizabethArden.com</p> <p>Made in U.S.A.</p>	<p>Elizabeth Arden</p>   <p>Eight Hour Cream Targeted Sun Defense Stick SPF 50 Sunscreen PA+++ NET WT. .24 OZ. 6.8 g</p>	<p>RECOMMENDED</p>  <p>SKIN CANCER FOUNDATION</p> <p>RECOMMENDED AS AN EFFECTIVE UV SUNSCREEN</p>
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EIGHT HOUR CREAM TARGETED SUN DEFENSE SPF 50

homosalate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.51 g in 6.8 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.51 g in 6.8 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.34 g in 6.8 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.27 g in 6.8 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.14 g in 6.8 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECYL MYRISTATE (UNII: S013N99GR8)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:67938-1130-1	1 in 1 BOX		
1	NDC:67938-1130-2	6.8 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/12/2010	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 1/2011

Elizabeth Arden, Inc