WHITE AND ELM EVERYDAY SPF 15- zinc oxide lotion White & Elm LLC

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.

Active Ingredient Listing

Active Ingredients: Zinc Oxide12%. Purpose: Sunscreen

Drug Facts

Active Ingredients Purpose Zinc Oxide 12% Sunscreen

Uses helps prevent sunburn

Warnings Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.

Directions

Apply generously and evenly 15 minutes before sun exposure. Children under 6 months of age: Ask a doctor.

Sun Protection Measures.

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

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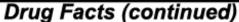
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Inactive Ingredients: Aloe Barbadensis (Aloe Vera) Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Glycerin (Vegetable), Cetearyl Olivate, Benzyl Alcohol, Sorbitan Olivate, Tocopherols (Vitamin E), Xanthan Gum, Dehydroacetic Acid



- reapply at least every 2 hours use a water-resistant sunscreen if swimming or sweating

Other Information protect the product in this container from excessive heat and direct sun. For external use only. Keep out of children's reach.

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whiteandelm.com Manufactured by White & Elm LLC crueltyfree andvegan plant based organic ingredients Fort Collins, CO 80525

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Drug Facts (continued)

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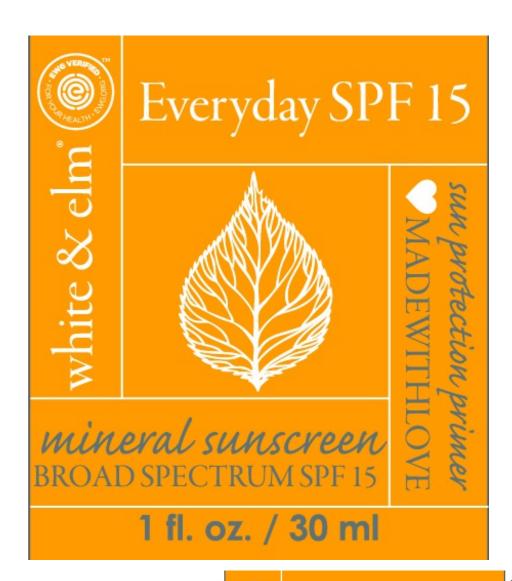
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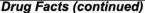
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Mineral Sunscreen **Broad Spectrum SPF 15**





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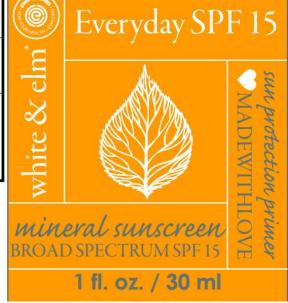
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WHITE AND ELM EVERYDAY SPF 15

zinc oxide lotion

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70840-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	146 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
SUNFLOWER OIL (UNII: 3W1JG795YI)				
ALOE (UNII: V5VD430 YW9)				
CETEARYL OLIVATE (UNII: 58B69Q84JO)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
TOCOPHEROL (UNII: R0ZB2556P8)				
XANTHAN GUM (UNII: TTV12P4NEE)				
GLYCERIN (UNII: PDC6A3C0OX)				
SORBITAN OLIVATE (UNII: MDL271E3GR)				
DEHYDRO ACETIC ACID (UNII: 2KAG279R6R)				

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:70840-001- 01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/09/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/09/2017	

Labeler - White & Elm LLC (074096784)

Establishment			
Name	Address	ID/FEI	Business Operations
White & Elm LLC		074096784	manufacture (70840-001)

Revised: 2/2017 White & Elm LLC