DR EDWARD KRULIG NEW MELAN SUNBLOCK SPF 50- avobenzone, octisalate, octocrylene liquid KRULIG INTERNATIONAL, INC

Dr. Edward Krulig New Melan Sunblock SPF 50

Drug Facts

Active Ingredient

Avobenzone 3.00%

Octisalate 5.00%

Octocrylene 10.00%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection
- Retains SPF after 80 minutes of swimming or sweating
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use

• on damaged or broken skin.

When using this product

- keep out of eyes. Rinse with water to remove.
- Do not puncture or incinerate. Contents under pressure.

Do not store it at temperatures above 120°F.

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.

If pregnant or breast-feeding,

Directions

- Apply liberally 15 minutes before sun exposure and as
- needed.
- Children under 6 months of age: ask a doctor.
- Reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- do not spray directly on face. Spray into hands and apply to face.
- Use in well-ventilated areas
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with broad spectrum SPF 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

Other Information

• Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Acrylates/Octylacrylamide Copolymer, Aloe Barbadensis Leaf (Aloe Vera) Extract, Ascorbyl Palmitate (Vitamin C), Butyloctyl Salicylate, Chamomilla Recutita (Chamomile) Extract, Cucumis Sativus (Cucumber) Fruit Extract, Helianthus Annuus (Sunflower) Oil, Parfum (Fragrance), SD-Alcohol 40B, Tocopheryl Acetate (Vitamin E).

Questions?

+34 645 66 06 12 For Europe +1 954 914 5722 For America

Package Labeling:





Drug Facts (continued)

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Distributed by Krulig International Inc, Pembroke Pines, FI +1 (954)914-5722

Middle **Bottom**

DR EDWARD KRULIG NEW MELAN SUNBLOCK SPF 50

avobenzone, octisalate, octocrylene liquid

Product Information

HUMAN OTC DRUG Product Type NDC:84857-545 **Item Code (Source)**

Route of Administration TOPICAL

Active Ingredient/Active Moiety Basis of Ingredient Name Strength Strength AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) **AVOBENZONE** 30 mg in 1 mL OCTISALATE (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE -OCTISALATE 50 mg in 1 mL UNII:4X49Y0596W) 100 mg OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) **OCTOCRYLENE** in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ASCORBYL PALMITATE (UNII: QN83US2B0N)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
CHAMOMILE (UNII: FGL3685T2X)				
CUCUMBER (UNII: YY7C30VXJT)				
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:84857-545- 00	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024		
Marketing Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

Labeler - KRULIG INTERNATIONAL, INC (131652883)

OTC Monograph Drug M020

Revised: 10/2024 KRULIG INTERNATIONAL, INC

10/14/2024