

AVON ELEMENTS SKIN REVITALIZE INSTANT RADIANCE- octinoxate, oxybenzone, homosalate, avobenzone lotion

New Avon 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 Ingredients

Octinoxate 7.5%.....
Oxybenzone 3.5%.....
Homosalate 3.0%.....
Avobenzone 2.5%.....

Purpose

..... Sunscreen
..... Sunscreen
..... Sunscreen
..... Sunscreen

Uses

- helps prevent sunburn

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.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply generously and evenly 15 minutes before sun exposure
- children under 6 month of age:ask a doctor
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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

Other Information


- protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

water/eau, propanediol, glycerin, DI-C12-15 alkyl fumarate, dilauryl thiodipropionate, PEG-8, steareth-2, silica, ethylhexyl isononanoate, steareth-21, aronia melanocarpa fruit juice, zizyphus jujuba fruit extract, petasites hybridus leaf extract, saccharomyces/platinum ferment, stearyl alcohol, acrylates/C10-30 alkyl acrylate crosspolymer, silica dimethyl silylate, polyester-1, PEG-200, polyurethane-40, carbomer, tromethamine, disodium EDTA, 1,2-hexanediol, caprylyl glycol, parfum/fragrance, iron oxides, mica/CI 77019, titanium dioxide/CI 77891.

Questions or comments?

Call toll free 1-800-FOR-AVON



Drug Facts

| Active ingredients | Purpose |
|----------------------|-----------|
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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10096-0302 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 35 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 30 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 25 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10096-0302-2 | 1 in 1 CARTON | | |
| 1 | NDC:10096-0302-1 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:10096-0302-3 | 1.1 mL in 1 PACKET; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 04/01/2013 | |

Labeler - New Avon LLC (080143520)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|-------------------------|
| Avon Products, Inc | | 005149471 | manufacture(10096-0302) |

Revised: 2/2016

New Avon LLC