

ZRII NEW DAY BROAD SPECTRUM SPF-30- avobenzone, homosalate, octinoxate, octocrylene, oxybenzone cream
ZRII, 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

Avobenzone 3.0%
Homosalate 5.0%
Octinoxate 5.0%
Octocrylene 2.7%
Oxybenzone 5.0%

PURPOSE

SUNSCREEN

USES

- Helps prevent sunburn
- 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.

Stop use and ask a doctor if rash occurs

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

DIRECTIONS

- Apply generously 15 minutes before sun exposure.
- Children under 6 months 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

Aqua, Carthamus Tinctorius (Safflower) Oleosomes, Glyceryl Stearate, Cetearyl Alcohol, Isodecyl Neopentanoate, Cetareth-20, Cetyl Alcohol, Niacinamide, Caprylic/Capric Triglycerides (and) Sea Whip Extract, Diisopropyl Sebacate, Lauryl Lactate, Ascorbyl Glucoside, Tocopheryl Acetate, 7-Dehydrocholesterol, Sodium Polyacrylate, Sodium Citrate, Carbomer, Hexylene Glycol, Disodium Edta, Sodium Hydroxide, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Citric Acid

QUESTIONS OR COMMENTS?

Call toll free 1-866-349-9911

<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> <tr> <td>Avobenzone 3.0%</td> <td rowspan="5">Sunscreen</td> </tr> <tr> <td>Homosalate 5.0%</td> </tr> <tr> <td>Octinoxate 5.0%</td> </tr> <tr> <td>Octocrylene 2.7%</td> </tr> <tr> <td>Oxybenzone 5.0%</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn 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. <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product, expect of eyes. Rinse with water to remove</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of the reach of children. If product is swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Apply generously 15 minutes before sun exposure. Children under 6 months of age: Ask a doctor. Rinse off 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: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. to 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses. <p>Other information</p> <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun. <p>Inactive ingredients</p> <p>Aqua, Carthamus Tinctorius (Safflower) Oleosomes, Glyceryl Stearate, Cetearyl Alcohol, Isodecyl Neopentanoate, Cetareth-20, Cetyl Alcohol, Niacinamide, Caprylic/Capric Triglycerides (and) Sea Whip Extract, Diisopropyl Sebacate, Lauryl Lactate, Ascorbyl Glucoside, Tocopheryl Acetate, 7-Dehydrocholesterol, Sodium Polyacrylate, Sodium Citrate, Carbomer, Hexylene Glycol, Disodium Edta, Sodium Hydroxide, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Citric Acid</p> <p>Questions or comments?</p> <p>Call toll free 1-866-349-9911</p> <p>NDC: 70528-018-11</p> <p>For lot number, see bottom of carton.</p> <p>MADE IN USA DISTRIBUTED BY: ZRII, LLC 14183 S HINQ TIGUAN DRIVE, CRAPER, UT 84020 101033 1881V1 02614 ZRII, LLC. WWW.ZRII.COM</p>	Active ingredients	Purpose	Avobenzone 3.0%	Sunscreen	Homosalate 5.0%	Octinoxate 5.0%	Octocrylene 2.7%	Oxybenzone 5.0%		<p>ZRII NEW™</p> <p>DAY CREAM BROAD SPECTRUM SPF 30 SUNSCREEN</p>  <p>1.7 FL. OZ./50 mL</p>	 <p>ENDORSED</p>
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ZRII NEW DAY BROAD SPECTRUM SPF-30

avobenzone, homosalate, octinoxate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70528-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
CETEARETH-22 (UNII: 28VZG1E234)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
NIACINAMIDE (UNII: 25X51I8RD4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
7-DEHYDROCHOLESTEROL (UNII: BK1IU07GKF)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70528-018-51	1 in 1 BOX	07/05/2016	
1	NDC:70528-018-11	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/05/2016	

Labeler - ZRII, LLC (807457531)

Establishment

Name	Address	ID/FEI	Business Operations
Westwood Laboratories Inc.		069926483	manufacture(70528-018)

Revised: 7/2016

ZRII, LLC