# ANEW REVERSALIST COMPLETE RENEWAL DAY- homosalate, octinoxate, oxybenzone, 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.

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## Anew Reversalist Complete Renewal Day Lotion Broad Spectrum SPF 25

## Active ingredient

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

#### **Directions**

- apply liberally 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:**

water/eau, butylene glycol, glycerin, dimethicone, PEG-8, trisiloxane, ethylhexyl isononanoate, HDI/trimethylol hexyllactone crosspolymer, cetyl alcohol, caprylyl glycol, behenyl alcohol, dilauryl thiodipropionate, thiodipropionic acid, carbomer, glyceryl stearate, parfum/fragrance, sodium

hydroxide, phenoxyethanol, trimethylsiloxysilicate, hydrogenated lecithin, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, polyglyceryl-3 diisostearate, choleth-24, hexylene glycol, ceteth-24, silica, amorphophallus campanulatus rhizome/root extract, punica granatum fruit juice, sesbania grandiflora flower extract, portulaca oleracea extract, palmitoyl lysyl aminovaleroyl lysine.

#### **Ouestions?**

1-800-FOR-AVON or **1-800-265-AVON** in Canada



# Drug Facts (continued)

crosspolymer, cetyl alcohol, caprylyl glycol, behenyl alcohol, dilauryl thiodipropionate, thiodipropionic acid, carbomer, glyceryl stearate, parfum/fragrance, sodium hydroxide, phenoxyethanol, trimethylsiloxysilicate, hydrogenated lecithin, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, polyglyceryl-3 diisostearate, choleth-24, hexylene glycol, ceteth-24, silica, amorphophallus campanulatus rhizome/root extract, punica granatum fruit juice, sesbania grandiflora flower extract, portulaca oleracea extract, palmitoyl lysyl aminovaleroyl lysine.

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#### **Drug Facts** Active ingredients Purpose Homosalate 8.0%..... Sunscreen Octinoxate 5.0%.....Sunscreen Oxybenzone 4.0%..... .Sunscreen Avobenzone 2.85%. Sunscreen 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.

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## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10096-0311

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.5 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:10096-0311- 2	1 in 1 CARTON	12/12/2013			
1	NDC:10096-0311-1	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product				
2	NDC:10096-0311-	1 in 1 CARTON	12/12/2013			
2	NDC:10096-0311-3	15 mL in 1 TUBE; Type 0: Not a Combination Product				
3	NDC:10096-0311- 5	1.1 mL in 1 PACKET; Type 0: Not a Combination Product	12/12/2013			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	12/12/2013		

# Labeler - New Avon LLC (080143520)

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