ANEW VITALE DAY- octinoxate, octisalate, oxybenzone, avobenzone cream
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.

Anew Vitale Day Cream Broad Spectrum SPF 25

Active Ingredients
Octinoxate 7.0%.....
Octisalate 4.5%.....
Oxybenzone 4.0%.....
Avobenzone 2.8%.....

Purpose
..... Sunscreen
..... Sunscreen
..... Sunscreen

..... 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

For sunscreen use:
- apply liberally 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, dimethicone, glycerin, PEG-8, butyloctyl salicylate, cetearyl alcohol, trisiloxane, dilauryl

thiodipropionate, phytol, behenyl alcohol,
thiodipropionic acid, panthenol, mesyloxybenzyl methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10, kaempferia galanga root extract, polysorbate 60, ceteareth-20, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, dimethicone crosspolymer, isohexadecane, carbomer, sodium hydroxide, disodium EDTA, caprylyl glycol, 1,2-hexanediol, parfum/fragrance.

Questions?
1-800-FOR-AVON or 1-800-265-AVON in Canada

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.0%	Sunscreen
Octisalate 4.5%	Sunscreen
Oxybenzone 4.0%	Sunscreen
Avobenzone 2.8%	Sunscreen

Drug Facts (continued)

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

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Drug Facts (continued)

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Directions

For sunscreen use:

Drug Facts (continued)
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Drug Facts (continued)

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

Inactive ingredients

water/eau, dimethicone, glycerin, PEG-8, butyloctyl salicylate, cetearyl alcohol, trisiloxane, dilauryl thiodipropionate, phytol, behenyl alcohol, thiodipropionic acid, panthenol, mesyloxybenzyl

Drug Facts (continued)

methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10, kaempferia galanga root extract, polysorbate 60, ceteareth-20, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, dimethicone crosspolymer, isohexadecane, carbomer, sodium hydroxide, disodium EDTA, caprylyl glycol, 1,2-hexanediol, parfum/fragrance.

Drug Facts (continued)

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

ANEW VITALE DAY

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10096-0319
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28 mg in 1 g

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10096-0319-2	1 in 1 CARTON	03/17/2014	
1	NDC:10096-0319-1	50 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10096-0319-4	1 in 1 CARTON	03/17/2014	
2	NDC:10096-0319-3	15 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:10096-0319-5	1.1 g in 1 PACKET; Type 0: Not a Combination Product	03/17/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/17/2014	

Labeler - New Avon LLC (080143520)

Revised: 1/2019 New Avon LLC