# ANEW VITALE 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 Vitale Day Lotion Broad Spectrum SPF 25**

#### **Active Ingredients**

...... Sunscreen

Homosalate 8.0%
Octinoxate 5.0%
Oxybenzone 4.0%
Avobenzone 2.85%
Purpose
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**

#### **IFor 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, butylene glycol, dimethicone, PEG-8, trisiloxane, glycerin, ethylhexyl isononanoate, HDI/trimethylol hexyllactone crosspolymer,

cetyl alcohol, caprylyl glycol, behenyl alcohol, dilauryl thiodipropionate, thiodipropionic acid, carbomer, glyceryl stearate, parfum/fragrance,

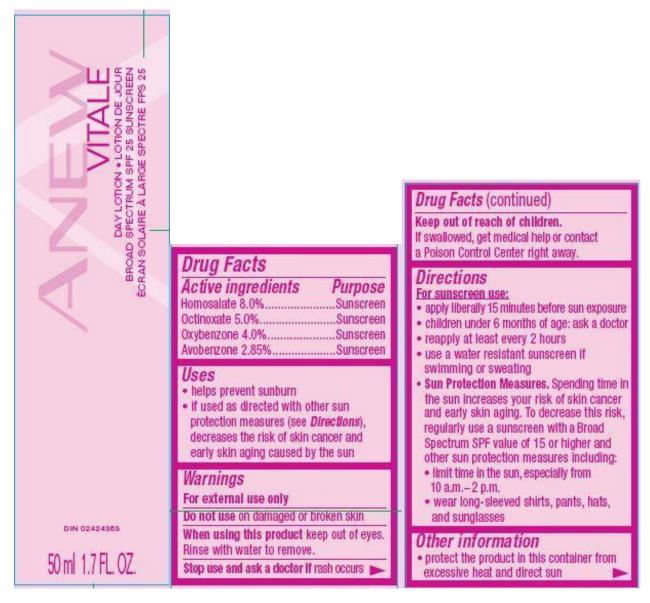
sodium hydroxide, phenoxyethanol, trimethylsiloxysilicate, hydrogenated lecithin, acrylates/C10-30 alkyl acrylate crosspolymer, disodium

EDTA, polyglyceryl-3 diisostearate, choleth-24, hexylene glycol, ceteth-24, panthenol, silica, mesyloxybenzyl methoxyethyl chlorobenzamide,

pichia ferment lysate filtrate, saccharomyces ferment lysate filtrate, palmitoyl tetrapeptide-10.

#### Questions?

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



### Drug Facts (continued)

### Inactive ingredients

water/eau, butylene glycol, dimethicone, PEG-8, trisiloxane, glycerin, 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, panthenol, silica, mesyloxybenzyl methoxyethyl chlorobenzamide, pichia ferment lysate filtrate, palmitoyl tetrapeptide-10.

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#### **ANEW VITALE DAY**

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10096-0322	
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)			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10096-0322-2	1 in 1 CARTON	12/19/2014	
1	NDC:10096-0322-1	50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10096-0322-4	1 in 1 CARTON	12/19/2014	
2	NDC:10096-0322-3	15 mL in 1 JAR; Type 0: Not a Combination Product		
3	NDC:10096-0322-5	1.1 mL in 1 PACKET; Type 0: Not a Combination Product	12/19/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/19/2014	

## Labeler - New Avon LLC (080143520)

Revised: 1/2019 New Avon LLC