

**HYDRATING ANTIOXIDANT MOITURIZER- avobenzone, homosalate, octisalate, octocrylene cream**

**Walgreen Company**

*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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**Active ingredients**

Avobenzone, 2.1%

Homosalate, 4.0%

Octisalate, 4.0%

Octocrylene, 2.0%

**Purpose**

Sunscreen

**Uses** •helps prevent sunburn •If used as directed with other 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.

**WARNINGS: FOR EXTERNAL USE ONLY.**

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE

THOROUGHLY WITH WATER. IF IRRITATION OR RASH OCCURS,

DISCONTINUE USE. KEEP OUT OF REACH OF CHILDREN.

IF SWALLOWED, SEEK MEDICAL ATTENTION OR CONTACT POISON CONTROL CENTER RIGHT AWAY.

**QUESTIONS OR COMMENTS?**

**call 1-800-925-4733**

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

**Directions**

•apply liberally 5 minutes before sun exposure

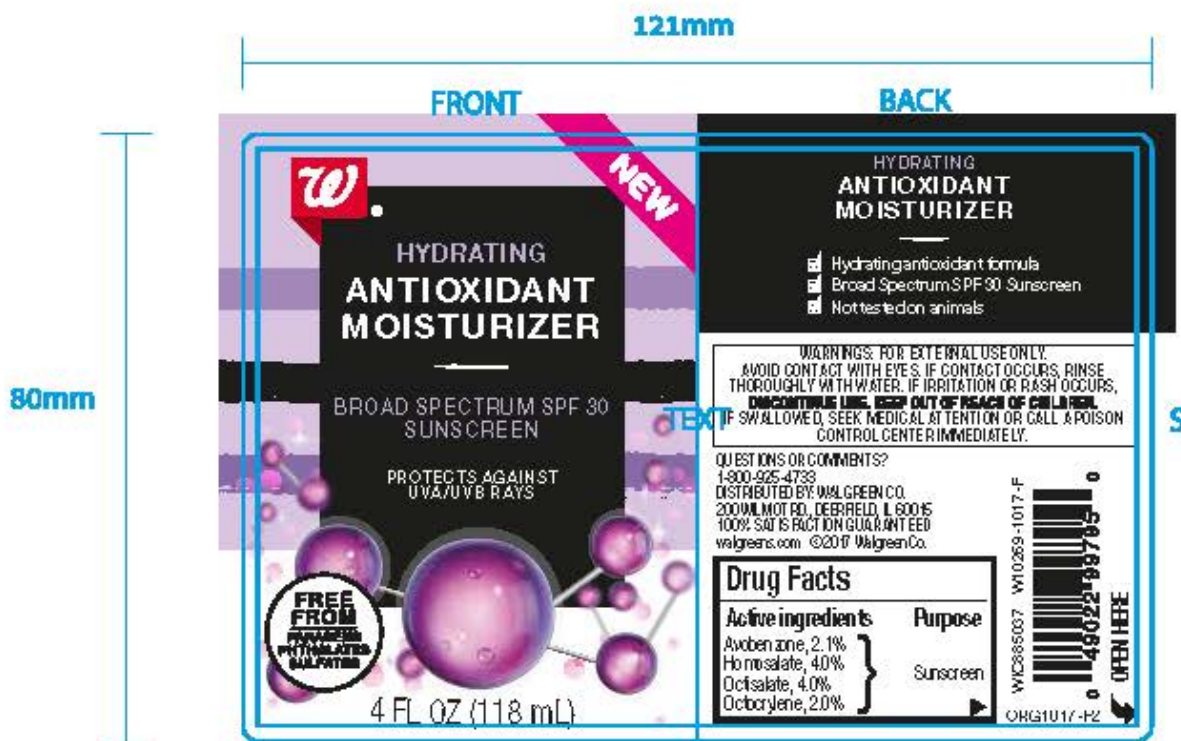
•reapply at least every 2 hours

- use water resistant sunscreen if swimming or sweating.
- children under 6 months of age: ask a doctor.
- 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, specially 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, Dimethicone, Trisiloxanane, Isononyl Isononanoate, Glycerin, Cetyl Alcohol, Steareth-21, Nylon-12, Silica, Stearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, Ethylhexylglycerin, Dimethicone Crosspolymer, Fragrance, Propylene Glycol, Myrtus Communis Extract, Xanthan Gum, Retinyl Palmitate, Polysorbate 20, Carbomer, Disodium EDTA, Ascorbic Acid, Sodium Hydroxide, ,BHT, Hyaluronic Acid.



**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.

**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.  
 • reapply at least every 2 hours.  
 • use water resistant sunscreen if swimming or sweating.  
 • children under 6 months of age: ask a doctor.

NO-INK ZONES

GLUE

**Drug Facts (continued)**

• 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, dimethicone, trisiloxane, isononyl isonanoate, glycerin, cetyl alcohol, steareth-21, nylon-12, silica, stearyl alcohol, glyceryl stearate, PEG-100 stearate, phenoxyethanol, ethylhexylglycerin, dimethicone crosspolymer, fragrance, propylene glycol, myrtus communis extract, xanthan gum, retinyl palmitate, polysorbate 20, carbomer, disodium EDTA, ascorbic acid, sodium hydroxide, BHT, hyaluronic acid.

**Questions or comments?** call 1-800-925-4733

NO-INK ZONES

## HYDRATING ANTIOXIDANT MOITURIZER

avobenzone, homosalate, octisalate, octocrylene cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0540
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.478 g in 118 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.72 g in 118 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	4.72 g in 118 mL
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6WM) (OCTOCRYLENE - UNII:5A68 WGF6WM)	OCTOCRYLENE	2.36 in 118 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TRISILOXANE</b> (UNII: 9G1ZW13R0G)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>MYRTUS COMMUNIS LEAF</b> (UNII: U20N87188F)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0540-01	118 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/28/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/28/2017	

**Labeler** - Walgreen Company (008965063)

