LAVELIER DIVINE DAY DEFENSE BROAD SPECTRUM SPF 30- octinoxate, homosalate, octisilate, oxybenzone and avobenzone cream
Florida Private Labeling 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.

Lavelier® Divine Day Defense Broad Spectrum SPF 30

Active Ingredients

Octinoxate 7.40%
Homosalate 6.20%
Octisalate 5.20%
Oxybenzone 3.10%
Avobenzone 1.50%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

For external use only. Do not use on damaged or broken skin.

Keep out of eyes. If contact occurs, rinse with water. If rash or irritation develops, discontinue use and consult your physician.

Stop using this product

and ask doctor if rash or redness develops and lasts.

Keep out of reach of children.

If accidental ingestion, call the Poison Control Center right away.

Directions

- After cleansing, apply liberally and evenly 15 minutes before sun exposure. Smooth over face and neck and chest daily for optimal results.
- Reapply at least every two (2) hours.

- Use 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

For children under 6 months of age: Ask doctor.

Other Information

Protect the product in this container from excessive heat and direct sun. Store at room temperature.

Inactive Ingredients

Aqua, C12-15 Alkyl Benzoate, Glycerin, Stearic Acid, Glyceryl Stearate, PEG-100 Stearate, Tocopherol, Retinyl Palmitate, Hydrolyzed Corallina Officinalis, Aloe Barbadensis Leaf Extract, Camellia Sinensis Leaf Extract, Sodium PCA, Polysorbate 60, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Disodium EDTA, Triethanolamine, Phenoxyethanol, Ethylhexylglycerin.

Package/Label Principal Display Panel

lavelier®

Divine Day Defense
BROAD SPECTRUM SPF 30
Divine Dèfense Jour
CORAL LUMINOUS | Brightening Collection

60g / 2.11oz

Label

LAVELIER DIVINE DAY DEFENSE BROAD SPECTRUM SPF 30

octinoxate, homosalate, octisilate, oxybenzone and avobenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73191-325
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.4 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6.2 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.2 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3.1 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
PALMITIC ACID (UNII: 2V16EO95H1)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73191-325-19	1 in 1 CARTON	08/01/2019	
1		60 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2019	

Labeler - Florida Private Labeling LLC (081081732)

Revised: 7/2022 Florida Private Labeling LLC