

VIVANT DAY TREATMENT SPF 15- octinoxate 7.50% octisalate 5.00% lotion
Vivant Pharmaceuticals, LLC

Vivant Day Treatment SPF 15

Active ingredients Purpose

Octinoxate 7.5%.....Sunscreen

Octisalate 5.0%.....Sunscreen

Sunscreen

Uses • helps prevent sunburn

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

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- 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 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-sleeve shirts, pants, hats, and sunglasses

Other information

- protect this product from excessive heat and direct sun.

Inactive ingredients

Water, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Emulsifying Wax, Caprylic/Capric Triglyceride, Octyldodecanol, Dimethicone, Aloe Barbadensis Leaf Juice, Saccharomyces/Zinc Ferment, Carbomer, Polysorbate 20, Titanium Dioxide, Disodium EDTA, Sodium Hydroxide, Potassium Sorbate, Ethylhexylglycerin, Phenoxyethanol

Day Treatment Lotion SPF 15

octinoxate 7.50% octisalate 5.00% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63750-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PEG-60 STEARATE (UNII: 7TB32G765E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63750-015-03	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/01/2024	

Labeler - Vivant Pharmaceuticals, LLC (782696814)

Establishment

Name	Address	ID/FEI	Business Operations
Vivant Pharmaceuticals, LLC		782696814	manufacture(63750-015)

Revised: 11/2024

Vivant Pharmaceuticals, LLC