

**LANCOME PARIS RENERGIE HPN 300 PEPTIDE BROAD SPECTRUM SPF 25
SUNSCREEN- avobenzone, octisalate and octocrylene cream
L'Oreal USA Products Inc**

Drug Facts

Active ingredients

Avobenzone 3%

Octisalate 5%

Octocrylene 7%

Purpose

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 generously and evenly 15 minutes before sun exposure
- 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
 - children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

water, glycerin, silica, dimethicone, isononyl isononanoate, propanediol, bis-PEG-18 methyl ether dimethyl silane, polyglyceryl-6 distearate, jojoba esters, tocopherol, limnanthes alba (meadowfoam) seed oil, cyclodextrin, hydrolyzed lupine protein, pisum sativum (pea) extract, adenosine, capryloyl salicylic acid, citric acid, disodium EDTA, hydrolyzed linseed extract, hydroxyacetophenone, scutellaria baicalensis root extract, sodium hyaluronate, sodium hydroxide, titanium dioxide, acacia decurrens flower wax, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, caprylyl glycol, cetyl alcohol, disodium stearyl glutamate, helianthus annuus (sunflower) seed wax, polyglycerin-3, polyglyceryl-3 beeswax, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, dimethiconol, benzyl alcohol, geraniol, limonene, red 33, phenoxyethanol, sodium benzoate, fragrance

Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses • children under 6 months of age: Ask a doctor <p>Other information</p> <ul style="list-style-type: none"> • protect the product in this container from excessive heat and direct sun <p>Inactive Ingredients</p> <p>water, glycerin, silica, dimethicone, isononyl isononanoate, propanediol, bis-PEG-18 methyl ether dimethyl silane, polyglyceryl-6 distearate, jojoba esters, tocopherol, limnanthes alba (meadowfoam) seed oil, cyclodextrin, hydrolyzed lupine protein, pisum sativum (pea) extract, adenosine, capryloyl salicylic acid, citric acid, disodium EDTA, hydrolyzed linseed extract, hydroxyacetophenone, scutellaria baicalensis root extract, sodium hyaluronate, sodium hydroxide, titanium dioxide, acacia decurrens flower wax, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, caprylyl glycol, cetyl alcohol, disodium stearyl glutamate, helianthus annuus (sunflower) seed wax, polyglycerin-3, polyglyceryl-3 beeswax, xanthan gum, dimethicone/vinyl dimethicone crosspolymer, dimethiconol, benzyl alcohol, geraniol, limonene, red 33, phenoxyethanol, sodium benzoate, fragrance</p> <p>Questions or comments? 1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST) V702277381 761589.89</p>	<p>LANCÔME PARIS</p>  <p>RÉNERGIE</p> <p>H.P.N. 300-PEPTIDE CREAM</p> <p>SUNSCREEN BROAD SPECTRUM SPF 25 HIGH-PERFORMANCE DAY CREAM</p> <p>[HYALURONIC ACID - 300 PEPTIDES - NIACINAMIDE]</p> <p>30 ml. 1 FL.OZ.</p> <p>MADE IN FRANCE LANCÔME.COM</p>	<p>PROVEN BY SCIENCE POWERED BY TECH</p>  <p>SCAN FOR YOUR PERSONALIZED SKIN DIAGNOSIS</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Azobenzene 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 7%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> • 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 <p>Warnings</p> <p>For external use only</p> <ul style="list-style-type: none"> • 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. <p>Directions</p> <p>For sunscreen use:</p> <ul style="list-style-type: none"> • apply generously and evenly 15 minutes before sun exposure • reapply at least every 2 hours 	Active ingredients	Purpose	Azobenzene 3%	Sunscreen	Octisalate 3%	Sunscreen	Octocrylene 7%	Sunscreen	<p>3614273924054 GENCOO (600) CCOCNE puno@peg sunlu SV</p>
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LANCOME PARIS RENERGIE HPN 300 PEPTIDE BROAD SPECTRUM SPF 25 SUNSCREEN

avobenzone, octisalate and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-240
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	70 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
PROPANEDIOL (UNII: 5965N8W85T)	
BIS-PEG-18 METHYL ETHER DIMETHYL SILANE (UNII: OEB4R3WW9C)	
POLYGLYCERYL-6 DISTEARATE (UNII: Z35I17EQOP)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
CYCLODEXTRINS (UNII: 7E6SK9QDT8)	
PEA (UNII: W4X7H8GYFM)	
ADENOSINE (UNII: K72T3FS567)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZ E9IY9)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	

XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNO)	
DIMETHICONOL (70 CST) (UNII: MOT8IL21AR)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-240-01	1 in 1 CARTON	06/01/2023	
1		50 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-240-02	1 in 1 CARTON	06/01/2023	06/01/2026
2		30 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:49967-240-03	1 in 1 CARTON	06/01/2023	
3		15 g in 1 JAR; Type 0: Not a Combination Product		
4	NDC:49967-240-04	1 in 1 CARTON	06/01/2023	
4		75 g in 1 JAR; Type 0: Not a Combination Product		
5	NDC:49967-240-05	1 g in 1 PACKET; Type 0: Not a Combination Product	06/01/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/01/2023	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-240) , pack(49967-240)

Establishment			
Name	Address	ID/FEI	Business Operations
BPS60		272259304	pack(49967-240)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-240)

Revised: 12/2023

L'Oreal USA Products Inc