

**HYDRA BEAUTE SPF 15- avobenzone, homosalate, octinoxate, octisalate, octocrylene cream**  
**Guinot**

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**HYDRA BEAUTE CREAM SPF 15**

***Drug Facts***

***Active ingredients***

Avobenzone 2.85%

Homosalate 5.00%

Octinoxate 7.00%

Octisalate 3.00%

Octocrylene 9.00%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see ), decreases the risk of skin cancer and early skin aging caused by the sun. **Directions**

***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 product is 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 a water resistant sunscreen if swimming or sweating.
  - 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: **Sun Protection Measures:**
  - Children under 6 months: Ask a doctor.
- Limit time in the sun, especially from 10 a.m. to 2 p.m.
- Wear long-sleeve shirts, pants hats, and sunglasses.

### ***Other information***

- Protect this product from excessive heat and direct sun.
- Store below 30°C/86°F.

### ***Inactive ingredients***

Water/Eau (Aqua), Glycerin, Cetyl Alcohol, Caprylic/Capric Triglyceride, Pentylene Glycol, Sodium Stearoyl Glutamate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polymethylsilsesquioxane, Caprylyl Methicone, HDI/Trimethylol Hexyllactone Crosspolymer, Hydrogenated Lecithin, Palmitic Acid, Propylene Glycol, Ethylhexylglycerin, Bisabolol, Oxidized Corn Oil, Tocopheryl Acetate, Stearalkonium Hectorite, Fragrance (Parfum), Xanthan Gum, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Betaine, Propylene Carbonate, Polysorbate 60, Sorbitan Isostearate, Disodium EDTA, Laminaria Ochroleuca Extract, Pectin, Butylene Glycol, Sucrose, Glyceryl Acrylate/Acrylic Acid Copolymer, Capryloyl Glycine, Sodium Hyaluronate, Red 4 (CI 14700). 01

### **Package Labeling:**



### Drug Facts (continued)

#### Inactive ingredients

Water/Eau (Aqua), Glycerin, Cetyl Alcohol, Caprylic/Capric Triglyceride, Pentylene Glycol, Sodium Stearoyl Glutamate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyethylsilsesquioxane, Caprylyl Methicone, HDI/Trimethylol Hexyllactone Crosspolymer, Hydrogenated Lecithin, Palmitic Acid, Propylene Glycol, Ethylhexylglycerin, Bisabolol, Oxidized Corn Oil, Tocopheryl Acetate, Stearalkonium Hectorite, Fragrance (Parfum), Xanthan Gum, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Betaine, Propylene Carbonate, Polysorbate 60, Sorbitan Isostearate, Disodium EDTA, Laminaria Ochroleuca Extract, Pectin, Butylene Glycol, Sucrose, Glyceryl Acrylate/Acrylic Acid Copolymer, Capryloyl Glycine, Sodium Hyaluronate, Red 4 (CI 14700).01

**GUINOT**  
INSTITUT • PARIS

CRÈME FPS 15  
**HYDRA  
BEAUTÉ**  
CREAM SPF 15

CRÈME HYDRATATION  
FPS 15 - LARGE SPECTRE  
VISAGE - PEAUX DÉSHYDRATÉES

MOISTURISING CREAM  
SPF 15 - BROAD SPECTRUM SUNSCREEN  
FACE - DEHYDRATED SKIN

**INGREDIENT**  
COMPLEXE HYDROCYTE  
HYDROCYTE COMPLEX

e 50 ml - NET WT 1.4 OZ

HYDRATATION | MOISTURISING

### Drug Facts

#### Active ingredients purpose

Avobenzone 2.85% ..... Sunscreen  
Homosalate 5.00% ..... Sunscreen  
Octinoxate 7.00% ..... Sunscreen  
Octisalate 3.00% ..... Sunscreen  
Octocrylene 9.00% ..... Sunscreen

#### Uses

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- 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.

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### Drug Facts (continued)

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  - Limit time in the sun, especially from 10 a.m. to 2 p.m.
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Réf. 0502804

Imported by Lachman Imports  
(800) 523-1030.

Guinot, 120 av. Charles de Gaulle, 92200 Neuilly-sur-Seine  
Made in France - 77190 Dammarie

CRÈME FPS 15  
**HYDRA  
BEAUTÉ**  
CREAM SPF 15

CRÈME HYDRATATION  
FPS 15 - LARGE SPECTRE  
VISAGE - PEaux DÉSHYDRATÉES  
MOISTURISING CREAM  
SPF 15 - BROAD SPECTRUM SUNSCREEN  
FACE - DEHYDRATED SKIN

**INGREDIENT**  
COMPLEXE HYDROCYTE  
HYDROCYTE COMPLEX

CRÈME HYDRATATION - FPS 15 - LARGE SPECTRE  
VISAGE - PEaux DÉSHYDRATÉES

Appliquer le matin sur l'ensemble du visage parfaitement propre.

MOISTURISING CREAM - SPF 15 - BROAD SPECTRUM  
SUNSCREEN - FACE - DEHYDRATED SKIN

Apply in the morning to the face after cleansing thoroughly.

FEUCHTIGKEITSCREME - LFS 15 - BREITBANDSPEKTRUM  
GESICHT - FEUCHTIGKEITSARME HAUT

Morgens auf das ganze, sorgfältig gereinigte Gesicht auftragen.

CREMA IDRATAZIONE - SPF 15 - AMPIO SPETTRO  
VISO - PELLI DISIDRATATE

Applicare il mattino sul viso perfettamente pulito.

CREMA HIDRATACIÓN - FPS 15 - AMPLIO ESPECTRO  
ROSTRO - PIELES DESHIDRATADAS

Aplicar por la mañana sobre el rostro perfectamente limpio.

كريم ترطيب - وقاية SPF15 - واسعة المدى - للوجه  
البشرة المفتقدة إلى الرطوبة

يستخدم صباحًا على كامل الوجه بعد تنظيفه جيدًا . صنع في فرنسا .



e 50 ml - NET WT 1.4 OZ

www.guinot.com

Guinot, 120 av. Charles de Gaulle  
92200 Neuilly-sur-Seine  
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**HYDRA BEAUTE SPF 15**

avobenzone, homosalate, octinoxate, octisalate, octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54181-009
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.5 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	90 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>STEARALKONIUM HECTORITE</b> (UNII: OLX698AH5P)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>PECTIN</b> (UNII: 89NA02M4RX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CAPRYLOYL GLYCINE</b> (UNII: 8TY5YO42NJ)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54181-009-50	1 in 1 BOX	01/01/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2019	

**Labeler** - Guinot (763667185)

## Establishment

Name	Address	ID/FEI	Business Operations
Guinot		763667185	manufacture(54181-009)

Revised: 10/2023

Guinot