

**FOTOSKINOX COLOR FACE CREAM SUNSCREEN BROAD SPECTRUM SPF 50-**  
**sunscreen cream**  
**HANS BIOMED S.L.**

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**Fotoskinox Color Face Cream Sunscreen Broad Spectrum SPF 50**

***Active Ingredient Purpose***

Avobnzone 3% Sunscreen

Ensulizole 3% Sunscreen

Octinoxate 4% Sunscreen

Octocrylene 2% Sunscreen

Titanium Dioxide 4.8% Sunscreen

***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

**Keep out of reach of children**

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

***Directions***

For sunscreen use:

Apply liberally 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. to 2 p.m.
- Wear long-sleeved shirts, pants, hats and, sunglasses.

Children under 6 months of age. Ask a doctor.

### ***Other Information***

Store at 15°C-30°C (59°F-86°F)

Protect the product in this container from excessive heat and direct sun

### ***Inactive Ingredients***

Water, Cyclopentasiloxane, Titanium Dioxide (CI 77891), Dicaprylyl Ether, Propanediol, Squalane, Ethyl Macadamiate, Butylene Glycol, Triethanolamine, Poly C10-30 Alkyl Acrylate, Sodium Polyacrylate, Cetyl Alcohol, Glyceryl Stearate, Phenoxyethanol, Yellow Iron Oxide (CI 77492), Glycerin, Cellulose Acetate, Red Iron Oxide (CI 77491), PEG-75 Stearate, Acrylates/Ammonium Methacrylate Copolymer, Propylene Glycol Stearate, Ceteth-20, Steareth-20, Lecithin, Gossypium Herbaceum Callus Culture, Silica, Ethylhexylglycerin, Magnesium Stearate, Black Iron Oxide (CI 77499), Polygonum Aviculare Extract, Hydrogenated Polydecene, Alteromonas Ferment Extract, Potassium Sorbat, Sodium Benzoate, Trideceth-6, Tocopherol, Citric Acid, Malic Acid, Acetyl Hexapeptide-49, Fragrance, Citronellol, D-Limonene, Geraniol, Linalool.

### ***Questions or comments?***

usa@skymedic.eu

### **OUTER PACKAGING**



**50+**

**FOTOSKINOX<sup>®</sup>**

**Color Face Cream  
Sunscreen**

**BROAD SPECTRUM  
SPF 50**

Multiprotection Broad Spectrum  
SPF 50

Physical and Mineral Sunscreens

**1.7 fl oz (50 mL)**

## Drug Facts

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Ensulizole 3%  
Octinoxate 4%  
Octocrylene 2%  
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## MADE IN SPAIN

### Manufactured by:

Hans Biomed, S.L.  
Isaac Peral 91 - 08224  
Terrasa (Spain)  
www.skymedic.eu

### Imported by:

Skymedic USA INC  
66 West Flagler Street, #900  
Miami, FL 33130, U.S.A.



## FOTOSKINOX COLOR FACE CREAM SUNSCREEN BROAD SPECTRUM SPF 50

sunscreen cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82601-300
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ENSULIZOLE</b> (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	3 mg in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 mg in 100 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 mg in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.8 mg in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)
<b>ETHYL MACADAMIATE</b> (UNII: ANA2NCS6V1)
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)
<b>PROPYLENE GLYCOL STEARATE</b> (UNII: MZM1I680W0)
<b>GERANIOL</b> (UNII: L837108USY)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>CETETH-20</b> (UNII: I835H2IHHX)
<b>GOSSYPIUM HERBACEUM FLOWER</b> (UNII: CVM893280N)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>DICAPRYLYL ETHER</b> (UNII: 77JZM5516Z)
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>POLYGONUM AVICULARE WHOLE</b> (UNII: M990N03611)
<b>HYDROGENATED POLYDECENE (1500 CST)</b> (UNII: 4YI0729529)
<b>ALTEROMONAS MACLEODII POLYSACCHARIDES</b> (UNII: AP6XG2GR8Z)
<b>MALIC ACID</b> (UNII: 817L1N4CKP)
<b>ACETYL HEXAPEPTIDE-49</b> (UNII: 4055X1S509)
<b>LINALOOL, (+)-</b> (UNII: F4VNO44C09)
<b>CELLULOSE ACETATE</b> (UNII: 3J2P07GVB6)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>PPG-1 TRIDECETH-6</b> (UNII: 1K7417JX6Q)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>WATER</b> (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82601-300-01	1 in 1 CARTON	07/01/2022	
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	07/01/2022	

**Labeler** - HANS BIOMED S.L. (464035248)

**Registrant** - AY CONSULTING SERVICES, LLC (078311971)

### Establishment

Name	Address	ID/FEI	Business Operations
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HANS BIOMED, S.L.

464035248

manufacture(82601-300)

Revised: 1/2024

HANS BIOMED S.L.