

**FOTOSKINOX FACE CREAM SUNSCREEN- avobenzonone, ensulizole, octinoxate, octocrylene, titanium dioxide cream
HANS BIOMED S.L.**

Fotoskinox Face Cream Sunscreen Broad Spectrum SPF 50

Active Ingredient Purpose

Avobenzonone 3%

Ensulizole 3%

Octinoxate 4% Sunscreen

Octocrylene 2%

Titanium Dioxide 2.6%

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

Warnings

Do not use on damaged or broken skin

Warnings

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 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 15C-30C (59F-86F).

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

Inactive Ingredients

Water, Cyclopentasiloxane, Butyl Methoxydibenzoylmethane Ethylhexyl Methoxycinnamate, Dicaprylyl Ether, Phenylbenzimidazole Sulfonic Acid, Propanediol, Squalane, Ethyl Macadamiate, Butylene Glycol, C8-22 Alkyl Acrylates/methacrylic Acid Crosspolymer, Triethanolamine, Cetyl Alcohol, Glyceryl Stearate, Sodium Polyacrylate, Phenoxyethanol, Glycerin, PEG-75 Stearate, Cetheth-20, Steareth-20, Lecithin, Yellow Iron Oxide (CI 77492), Gossypium Herbaceum Callus Culture, Silica, Ethylhexylglycerin, Red Iron Oxide (CI 77491), Polygonum Aviculare Extract, Black Iron Oxide (CI 77499), Alteromonas Ferment Extract, Citric Acid, Potassium Sorbate, Sodium Benzoate, Tocopherol, Malic Acid, Acetyl Hexapeptide-49, Fragrance, Citronellol, D-Limonelle, Hydroxycitronellal, Linalool, Geraniol.

Questions or comments?

usa@skymedic.eu

OUTER PACKAGING



50+

FOTOSKINOX

**Face Cream
Sunscreen**

**BROAD SPECTRUM
SPF 50**

Multiprotection Broad Spectrum
SPF 50

Physical and Mineral Sunscreens

1.7 fl oz (50 mL)

50 mL NDC 82601-200-01

Drug Facts

Active Ingredient

Avobenzone 3%
Ensulizole 3%
Octinoxate 4%
Octocrylene 2%
Titanium Dioxide 4.8%

Purpose

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- Helps prevent sunburn

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 - 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 Sorbate, Sodium Benzoate, Trideceth-6, Tocopherol, Citric Acid, Malic Acid, Acetyl Hexapeptide-49, Fragrance, Citronellol, D- Limonene, Geraniol, Linalool.

Questions or comments?

usa@skymedic.eu

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 FACE CREAM SUNSCREEN

avobenzone, ensulizole, octinoxate, octocrylene, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82601-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mL
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	3 mg in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 mg in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 mg in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.6 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETETH-20 (UNII: I835H2IHHX)	

HYDRATED SILICA (UNII: Y6O7T4G8P9)
POLYGONUM AVICULARE WHOLE (UNII: M990N03611)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
LINALOOL, (+)- (UNII: F4VNO44C09)
DICAPRYLYL ETHER (UNII: 77JZM5516Z)
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
CETYL ALCOHOL (UNII: 936JST6JCN)
GOSSYPIUM HERBACEUM FLOWER (UNII: CVM893280N)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GLYCERIN (UNII: PDC6A3C0OX)
PEG-75 STEARATE (UNII: OT38R0N74H)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
SQUALANE (UNII: GW89575KF9)
STEARETH-20 (UNII: LQ8IK9E08)
ALTEROMONAS MACLEODII POLYSACCHARIDES (UNII: AP6XG2GR8Z)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
TOCOPHEROL (UNII: R0ZB2556P8)
MALIC ACID (UNII: 817L1N4CKP)
ACETYL HEXAPEPTIDE-49 (UNII: 4055X1S509)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
GERANIOL (UNII: L837108USY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82601-200-01	1 in 1 CARTON	06/30/2022	
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	06/30/2022	

Labeler - HANS BIOMED S.L. (464035248)

Registrant - AY CONSULTING SERVICES, LLC (078311971)

Establishment

Name	Address	ID/FEI	Business Operations
HANS BIOMED , S.L.		464035248	manufacture(82601-200)

