

**ELIXIR FINE SUNSCREEN BROAD SPECTRUM SPF 15- avobenzone, octinoxate, octocrylene cream  
IXXI S.A.S.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Elixir FINE EMULSION CREAM Sunscreen Broad Spectrum SPF 15**

***Drug Facts***

***Active ingredients***

Avobenzone 3%

Octinoxate 7.5%

Octocrylene 7.5%

***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***

- 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. - 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 and direct sun.

### ***Inactive ingredients***

water (aqua), coco-caprylate/caprato, cetearyl alcohol, glyceryl stearate citrate, pentylene glycol, propanediol, sodium stearyl glutamate, butylene glycol, sodium polyacrylate, jojoba esters, glycerin, sunflower (Helianthus annuus) seed oil, sucrose laurate, sunflower (Helianthus annuus) seed cera/wax, hydrogenated starch hydrolysate, fragrance (parfum), ethylhexylglycerin, palmitoyl pine bark extract, chlorphenesin, xanthan gum, sucrose dilaurate, tocopherol, maritime pine (Pinus pinaster) bark extract, sucrose trilaurate, green wattle (Acacia decurrens) flower cera/wax, polyglycerin-3, apple (Pyrus malus) fruit extract, wild soybean (Glycine soja) oil, sodium phytate, palmitic acid, male fern (Dryopteris filis-mas) root extract, citric acid, BHT, sodium benzoate, potassium sorbate, ursolic acid, alcohol, sodium hydroxide.

### ***Questions?***

Call toll-free 1-800-322-3507

### ***Package Labeling:***

THE IDEAL CARE PRODUCT TO  
HYDRATE THE SKIN.  
SKIN APPEARS RADIANT.  
NON-COMEDOGENIC.  
DERMATOLOGICALLY TESTED.

### Drug Facts

Active ingredients	Purpose
Avobenzone 3% Octinoxate 7.5% Octocrylene 7.5%	Sunscreen

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  - 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 (aqua), coco-caprylate/caprate, cetyl alcohol, glyceryl stearate citrate, pentaerythritol, propenediol, sodium stearoyl glutamate, butylene glycol, sodium polyacrylate, jojoba esters, glycerin, sunflower (Helianthus annuus) seed oil, sucrose laurate, sunflower (Helianthus annuus) seed cerawax, hydrogenated starch hydrolysate, fragrance (parfum), ethylhexylglycerin, palmitoyl pine bark extract, chlorophanesin, xanthan gum, sucrose octalaurate, tocopherol, maritime pine (Pinus pinaster) bark extract, sucrose tribaurate, green wattle (Acacia decurrens) flower cerawax, polyglycerin-3, apple (Pyrus malus) fruit extract, wild soybean (Glycine soja) oil, sodium phytate, palmitic acid, male fern (Dryopteris filix-mas) root extract, citric acid, BHT, sodium benzoate, potassium sorbate, ursolic acid, alcohol, sodium hydroxide.

**Questions?** Call toll-free 1-800-322-3507

Manufactured for:

IXXI S.A.S

1078 route Andre Dupuy CS 60030  
F-40260 CASTETS, FRANCE

Distributed by:

COSMETIC IMPORTS MARKETING GROUP Inc.  
2332 State Route 11 #402  
Moers, New York, 12958

MADE IN FRANCE

To report a serious adverse event contact:  
Cosmetic Imports Marketing Group, Inc.  
2332 State Route 11 # 402  
Moers, NY 12958

IXXI



Elixir

FINE EMULSION  
CREAM

Sunscreen  
Broad Spectrum  
SPF 15

SKIN LOOKS MOISTURIZED

ALL SKIN TYPES

1.7 fl oz (50 ml e)

REF: 6519

LOT:



3 700677 765192

6381/319/2013.1

## ELIXIR FINE SUNSCREEN BROAD SPECTRUM SPF 15

avobenzone, octinoxate, octocrylene cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70532-001
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 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	75 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CO CO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SUCROSE LAURATE (UNII: 05Q7CD0E49)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCROSE DILAURATE (UNII: 5926LC4S7M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MARITIME PINE (UNII: 50JZ5Z98QY)	
ACACIA DECURRENS FLOWER WAX (UNII: AU6XZE9IY9)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
PALMITIC ACID (UNII: 2V16EO95H1)	
DRYOPTERIS FILIX-MAS ROOT (UNII: C0ZK0RRF5X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
URSOLIC ACID (UNII: P3M2575F3F)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70532-001-01	1 in 1 CARTON	04/03/2016	
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination		

Product			
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	04/01/2016	

**Labeler** - IXXI S.A.S. (263290505)

Revised: 4/2016

IXXI S.A.S.