

LIGHTENING HIGH SUN PROTECTION CREAM- octocrylene, titanium dioxide, avobenzone cream

Casmara Cosmetics, SA

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.

Lightening High Sun Protection Cream

ACTIVE INGREDIENTS PURPOSE

Octocrylene 10%..... Sunscreen
 Titanium Dioxide 5.1%..... Sunscreen
 Avobenzone 4%..... Sunscreen

CASMARA
 BeautyPlanPremium

lightening

HIGH SUN PROTECTION
 CREAM

CRÈME DE PROTECTION
 CONTRE LE SOLEIL

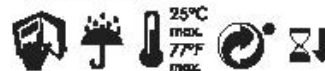
SUNSCREEN TO HELP
 PREVENT SUNBURN. S.P.F. 50


 FACIAL COLLECTION

50 ml 1.7 fl.oz.

CASMARA COSMETICS, S.A. - Cod. AMA30003TR
 C/ CIUTAT DE LLURIA, n° 29 y 31 · POL. IND. FUENTE DEL JARRO · 46988 PATERNA · (VALENCIA) SPAIN
 TEL. (+34) 961 501 999 · Fabr. n° 00690CS
 www.casmara.com · casmara@casmara.es · MADE IN SPAIN (EU)

Drug Facts	
Active ingredient	Purpose
Octocrylene 10 %	Sunscreen
Titanium dioxide 5,1 %	Sunscreen
Avobenzone 4 %	Sunscreen
Indications	
· provides high protection against sunburns. · Sunscreen to help prevent the sunburns. Filters the sun rays to help prevent the skin damages.	
Warnings	
"SUN ALERT: The sun causes skin damages. Regular use of sunscreens over the years may reduce the risks of skin damages, some types of skin cancer, and other harmful defects due to the sun." For external use only, not to be swallowed. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Discontinue uses if signs of irritation or rash appears. If irritation or rash persists, consult with a doctor. Keep out of reach of children. Children under 6 months: ask a doctor.	
Directions	
· adults and children 6 months of age and over: apply generously before sun exposure. Reapply after swimming, excessive sweating or anytime after towel drying. Children under 2 years of age should use sunscreen products with a minimum of SPF 4. · children under 6 months of age, consult with a doctor.	
Other information	
· Protect this product from excessive heat and direct sun.	
Inactive ingredients	
water, glycerin, butylene glycol dicaprylate/dicaprate, ethylhexyl salicylate, alcohol denat, benzotriazinol, polysilicone-15, cetyl alcohol, glyceryl stearate, phenoxethanol, PEG-75 stearate, silica, xanthan gum, butylene glycol, ceteth-20, steareth-20, dimethicone, ethylhexylglycerin, tetrazodium glutamate diacetate, fragrance, soybean protein.	
Questions or comments?	
· +34 961 501999 M-F 9:00 am to 5:00 pm "SUN ALERT: limiting sun exposures. Wearing protective clothing and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun."	



Cod. A30003V

Warnings

SUN ALERT: The sun causes skin damages. Regular use of sunscreens over the years may reduce the risks of skin damages, some types of skin cancer, and other harmful effects due to the sun

For external use only, not to be swallowed.

Do not use on damaged or broken skin.

When using this product keep our of the eyes. Rinse with water to remove.

Discontinue uses if signs or irritations or rash appears. If irritation or rash persists, consult with a doctor.

Keep out of reach of children.

Children under 6 months: as a doctor.

WARNINGS

Stop use and ask a doctor if rash occurs

Children under 6 months: ask a doctor

Warnings

Keep out of reach of children

Questions or comments?

+ 34 961 501 999 M-F 9:00 am to 5:00 pm

Other Information

. keep the product in a cool and dry place

Directions

- adults and childrens 6 months of age and over: apply generously before sun exposure. Reapply after swimming, excessive sweating or anytime after towel drying. Children under 2 years of age or less should use sunscreen products with a minium of SPF 4
- children under 6 months of age, consult with a doctor
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- children under 6 months of age, consult with a doctor

Uses

- provides high protection against sunburns
- sunscreen to help prevent sunburns. Filters the sun rays to help prevent the skin damages

Inactive Ingredients

Water, Glycerin, Butylene glycol dicaprylate/dicaprate, Ethylhexyl salicylate, Alcohol denat, Bemotrizinol, Polysilicone-15, Cetyl alcohol, Glyceryl stearate, Phenoxyethanol, PEG-75 stearate, Silica, Xanthan gum, Butylene glycol, Ceteth-20, Steareth-20, Dimethicone, Ethylhexylglycerin, Tetrasodium glutamate diacetate, Fragrance, Soybean protein

Uses

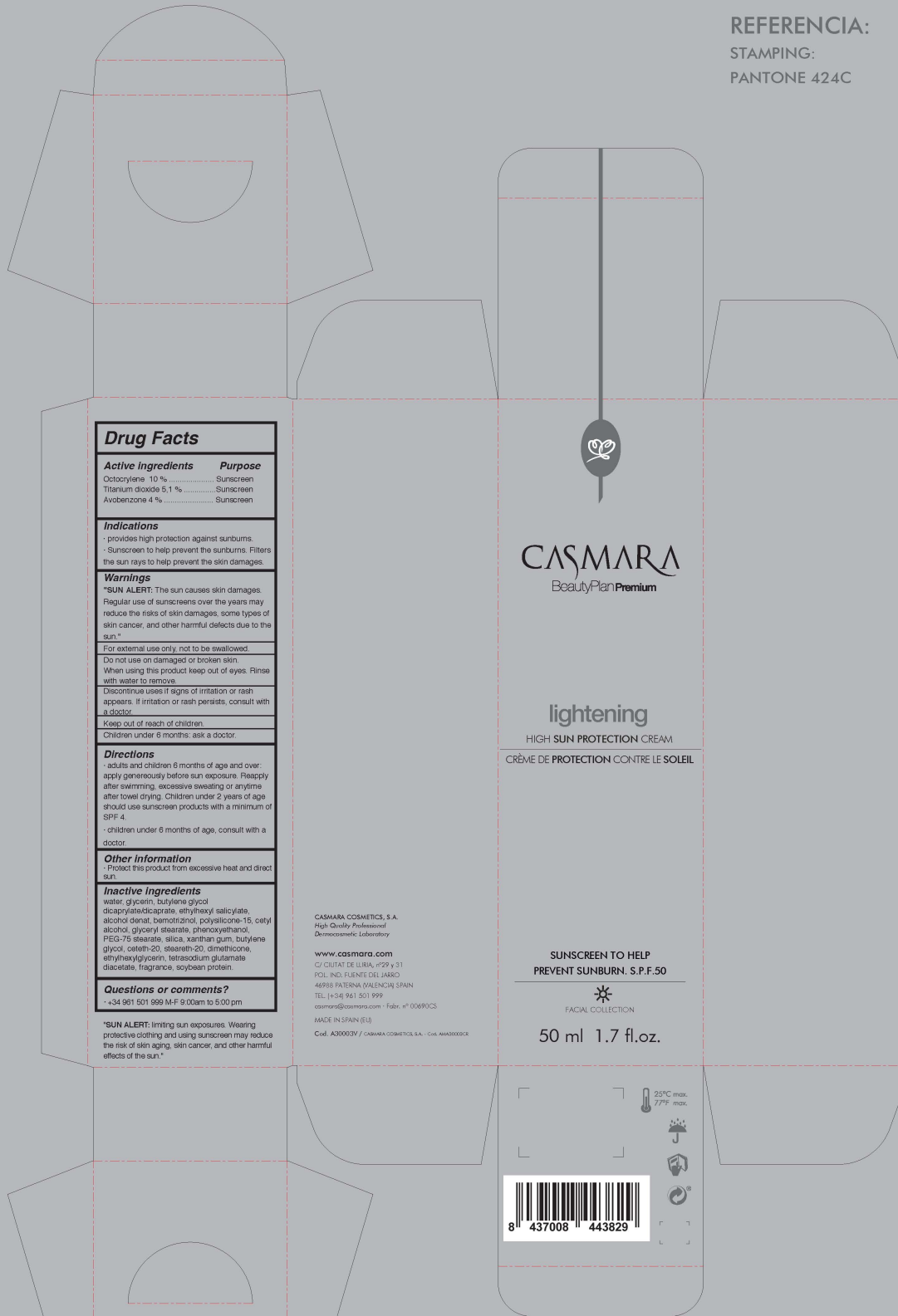
- provides high protection against sunburns
- sunscreen to help prevent sunburns. Filters the sun rays to help prevent the skin damages

Package Label

REFERENCIA:

STAMPING:

PANTONE 424C



Drug Facts

Active ingredients	Purpose
Octocrylene 10 %	Sunscreen
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Avobenzona 4 %	Sunscreen

Indications

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- Sunscreen to help prevent the sunburns. Filters the sun rays to help prevent the skin damages.

Warnings

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When using this product keep out of eyes. Rinse with water to remove.

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Children under 6 months: ask a doctor.

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- children under 6 months of age, consult with a doctor.

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

water, glycerin, butylene glycol, dicaprylate/dicaprate, ethylhexyl salicylate, alcohol denat, benzotriazol, polysilicone-15, cetyl alcohol, glyceryl stearate, phenoxyethanol, PEG-75 stearate, silica, xanthan gum, butylene glycol, ceteal-20, steareth-20, dimethicone, ethylhexylglycerin, tetrasodium glutamate diacetate, fragrances, isobutyl protein.

Questions or comments?

+34 961 501 999 M-F 9:00am to 5:00 pm

***SUN ALERT:** limiting sun exposures. Wearing protective clothing and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.*

CASMARA COSMETICS, S.A.
High Quality Professional
Dermocosmetic Laboratory

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MADE IN SPAIN (EU)

Cod. A30093V / CASMARA COSMETICS S.A. - Cód. 99480000C

CASMARA
BeautyPlanPremium

lightening

HIGH SUN PROTECTION CREAM

CRÈME DE PROTECTION CONTRE LE SOLEIL

SUNSCREEN TO HELP
PREVENT SUNBURN. S.P.F.50



FACIAL COLLECTION

50 ml 1.7 fl.oz.

25°C max.
77°F max.



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LIGHTENING HIGH SUN PROTECTION CREAM

octocrylene, titanium dioxide, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20 151-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	5.1 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	4 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6WM) (OCTOCRYLENE - UNII:5A68 WGF6WM)	OCTOCRYLENE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	0.12 mg in 1 mL
SOYBEAN (UNII: L7HT8FIZOD)	0.02 mg in 1 mL
CETETH-20 (UNII: I835H2IHHX)	0.372 mg in 1 mL
STEARETH-20 (UNII: L0Q8IK9E08)	0.372 mg in 1 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.5 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596W)	5 mg in 1 mL
POLYSILICONE-15 (UNII: F8DRP5BB29)	3 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.1 mg in 1 mL
WATER (UNII: 059QF0K00R)	43.56 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M)	4.8 mg in 1 mL
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI)	5 mg in 1 mL
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	0.094 mg in 1 mL
BEMOTRIZINOL (UNII: PWZ1720CBH)	4 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	7 mg in 1 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	1.87 mg in 1 mL
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	1.875 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 1 mL
PEG-75 STEARATE (UNII: OT38R0N74H)	0.872 mg in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.78 mg in 1 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.6 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20 151-105-02	1 in 1 BOTTLE, DISPENSING	04/01/2017	
1	NDC:20 151-105-01	50 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/29/2017	

Labeler - Casmara Cosmetics, SA (464973544)

Registrant - Casmara Cosmetics, SA (464973544)

Establishment

Name	Address	ID/FEI	Business Operations
Casmara Cosmetics, SA		464973544	manufacture(20151-105)

Revised: 6/2017

Casmara Cosmetics, SA