

**CREMA NERA EXTREMA SPF 14- avobenzone, homosalate, octisalate, octocrylene cream
BPS 60**

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.

Crema Nera Extrema SPF 14

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 7%

Octisalate 5%

Octocrylene 7%

Purpose

Sunscreen

Use

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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
- 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, glycerin, bifida ferment lysate, silica, alcohol denat., dimethicone, isopropyl lauroyl sarcosinate, styrene/acrylates copolymer, PEG-100 stearate, glyceryl stearate, tocopherol, synthetic wax, tamarindus indica seed polysaccharide, camellia oleifera seed oil, myrothamnus flabellifolia leaf extract, PEG-8 laurate, dicaprylyl carbonate, stearic acid, stearyl alcohol, potassium chloride, nigella sativa seed oil, triethanolamine, dimethicone/vinyl dimethicone crosspolymer, trehalose, methylsilanol mannuronate, sodium lactate, myristic acid, myristyl alcohol, rhamnose, palmitic acid, adenosine, magnesium sulfate, ascorbyl glucoside, ammonium polyacryloyldimethyl taurate, disodium EDTA, disodium phosphate, capparispinosa fruit extract, capryloyl salicylic acid, caprylyl glycol, citric acid, xanthan gum, scutellaria baicalensis root extract, t-butyl alcohol, cetyl alcohol, octyldodecyl myristate, sorbic acid, sodium benzoate, phenoxyethanol, linalool, geraniol, alpha-isomethyl ionone, citronellol, hexyl cinnamal, benzyl alcohol, benzyl salicylate, fragrance

Package Labeling:



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Homosalate 7%	Sunscreen
Octisalate 3%	Sunscreen
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Questions or comments? Contact: GIORGIO ARMANI PARFUMS, L'EXILY PRODUCTS LLC, 10 HUDSON YARDS, NEW YORK, NY 10001
 FOR MORE INFORMATION ON THIS WEBSITE: WWW.ARMANYBEAUTY.COM

GIORGIO ARMANI
CREMA NERA EXTREMA

essential defense fluid
Sunscreen
 Broad Spectrum SPF 14
 e 30 ml 1.01 FL.OZ.

ANS 026188-001-01 13E0182A1



SANS DATAMATRIX, AVEC SEAL VECTOR

1841781

DERMATOLOGICALLY TESTED.
 THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS GIORGIO ARMANI PARFUMS, 16 PLACE VENDÔME, 75001 PARIS
 L'EXILY PRODUCTS LLC, NEW YORK, NY 10001
 IMP. BY DESIGNER FRAGRANCES, MONTRÉAL, QUÉBEC, CANADA, H3T 1K5
 TSA 75000 B1685 ST OLEN CEDEX, FR - MADE IN FRANCE.



CREMA NERA EXTREMA SPF 14

avobenzene, homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 58 1-0 10
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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	70 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL LAUROYL SARCO SINATE (UNII: LYR06W430J)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
MYROTHAMNUS FLABELLIFOLIA LEAF (UNII: 6Y9E0R40J5)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
TROLAMINE (UNII: 9O3K93S3TK)	
TREHALOSE (UNII: B8WCK70T7I)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
MYRISTIC ACID (UNII: 0BV7S25AW)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
RHAMNOSE (UNII: QN34XC755A)	
PALMITIC ACID (UNII: 2V16EO95H1)	
ADENOSINE (UNII: K72T3FS567)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
EDETATE DISODIUM ANHYDRO US (UNII: 8NLQ36F6MM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)	
CAPER BERRY (UNII: 7G4C45EE8C)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OCTYLDODECYL MYRISTATE (UNII: S013N99GR8)	
SORBIC ACID (UNII: X045WJ989B)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
GERANIOL (UNII: L837108USY)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70581-010-00	1 in 1 BOX	12/25/2017	
1		30 mL in 1 BOTTLE; 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	12/25/2017	

Labeler - BPS 60 (272259304)

Revised: 12/2019

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