

ULTIMATE PRO-COLLAGEN DAY AND NIGHT DUO- avobenzone, octinoxate, and octocrylene
Elemis Ltd.

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.

ULTIMATE PRO-COLLAGEN DAY & NIGHT DUO
Avobenzone, Octinoxate, Octocrylene

Drug Facts

Active ingredients

Avobenzone 1.0% }
Octinoxate 1.0% }
Octocrylene 0.5% }

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection

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 and evenly 15 minutes before sun exposure and as needed
- children under 6 months of age: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin ageing. 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
 - reapply at least every 2 hours

- use a water resistant sunscreen if swimming or sweating

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

Water, Glycerin, Caprylic/Capric Triglyceride, Glyceryl Stearate SE, Isononyl Isononanoate, Dicaprylyl Carbonate, Dimethicone, Phenoxyethanol, Polyacrylate-13, Butylene Glycol, Cetyl Alcohol, Hydroxyacetophenone, Stearic Acid, Tocopheryl Acetate, Coco-Caprylate, Xanthan Gum, Chlorphenesin, Polyisobutene, Fragrance, Disodium EDTA, Lecithin, Tocopherol, Butyrospermum Parkii (Shea) Butter, Daucus Carota Sativa (Carrot) Root Extract, Triticum Vulgare (Wheat) Germ Oil, Chlorella Vulgaris Extract, Glyceryl Polyacrylate, Glyceryl Acrylate/Acrylic Acid Copolymer, Padina Pavonica Thallus Extract, Sodium Dehydroacetate, Polysorbate 20, Sorbitan Isostearate, Ginkgo Biloba Leaf Extract, Porphyridium Cruentum Extract, Acacia Decurrens (Mimosa) Flower Extract, Rosa Centifolia (Rose) Flower Extract, Sodium Benzoate, Potassium Sorbate, Citric Acid.

Questions?

US T: 1-855-235-3647

PRINCIPAL DISPLAY PANEL - Kit Container

ULTIMATE PRO-COLLAGEN
DAY & NIGHT DUO

Pro-Collagen Marine Cream SPF 30
Broad Spectrum SPF 30 | Sunscreen
Pro-Collagen Overnight Matrix

NET WT. 2x 50ml e 1.6 US fl. oz.

ELEMIS

23421



Pro-Collagen Overnight Matrix
50ml e 1.6 US fl. oz.

Pro-Collagen Marine Cream SPF 30
50ml e 1.6 US fl. oz.

KIT INCLUDES:

Pro-Collagen Marine Cream helps hydrate the skin and reduce the appearance of fine lines and wrinkles. Whilst Pro-Collagen Overnight Matrix is formulated with Drone Peptide Technology to leave skin looking smooth, with visible bounce-back.

Harness the deeply hydrating power of ELEMIS' rich marine actives with this iconic Pro-Collagen duo.

**ULTIMATE PRO-COLLAGEN
DAY & NIGHT DUO**

Drug Facts
Active ingredients: Azoberzone 1.0%, Octinoxate 1.0%, Octocrylene 0.5%
Purpose: Sunscreen
Uses • helps prevent sunburn • higher SPF gives more sunburn protection
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 and evenly 15 minutes before sun exposure and as needed • children under 6 months of age: Ask a doctor • 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 • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating
Other information • protect the product in this container from excessive heat and direct sun
Inactive ingredients: Water, Glycerin, Caprylic/Capric Triglyceride, Glyceryl Stearate SE, Isomonyl Isnonanoate, Dicaprylyl Carbonate, Dimethicone, Phenoxethanol, Polyacrylate-E3, Butylene Glycol, Cetyl Alcohol, Hydroxyacetophenone, Stearic Acid, Tocopherol Acetate, Coco-Caprylate, Xanthan Gum, Chlorphenesin, Polybutene, Fragrance, Disodium EDTA, Lecithin, Tocopherol, Butyrospermum Partii (Shea) Butter, Daucus Carota Sativa (Carrot) Root Extract, Triticum Vulgare (Wheat) Germ Oil, Chlorella Vulgare Extract, Glyceryl Polyacrylate, Glyceryl Acrylate/Acrylic Acid Copolymer, Padina Pavonica Thallus Extract, Sodium Dehydroacetate, Polyorbate 20, Sorbitan Isostearate, Ginkgo Biloba Leaf Extract, Porphyrindium Cruentum Extract, Acacia Decurrens (Mimos) Flower Extract, Rosa Centrifolia (Rose) Flower Extract, Sodium Benzoate, Potassium Sorbate, Citric Acid.
Questions? US 1-855-235-3647

PRO-COLLAGEN MARINE CREAM SPF 30



**ULTIMATE PRO-COLLAGEN
DAY & NIGHT DUO**

*Pro-Collagen Marine Cream SPF 30
Broad Spectrum SPF 30 | Sunscreen*

Broad Spectrum SPF 50+ Sunscreen
Pro-Collagen Overnight Matrix

ELEMIS

NET WT. 2x 50ml e 1.6 US fl. oz.

Pro-Collagen Overnight Matrix 50ml e 1.6 US fl. oz.

INGREDIENTS: Aqua/Water/Eau, Glycerin, Oils/Vegetable Oil/Huile Végétale, Propanediol, Behenyl Alcohol, Squalane, Butylene Glycol, Octyldodecanol, Dicaprylyl Carbonate, Helianthus Annuus (Sunflower) Seed Oil, Phenoxethanol, Acrylates/C10-30 Alkyl Acrylate Copolymer, Beheneth-25, Glyceryl Acrylate/Acrylic Acid Copolymer, Benzoic Acid, Lavandula Angustifolia (Lavender) Oil, Disodium EDTA, Dunaliella Salina Extract, Rhizobian Gum, Sodium Hyaluronate, Dehydroacetic Acid, Linalool, Lavandula Hybrid Oil, Pelargonium Graveolens Flower Oil, Padina Pavonica Thallus Extract, Geraniol, Eucalyptus Globulus Leaf Oil, Chlorphenesin, Plankton Extract, Anthemis Nobilis Flower Oil, Citronellol, Potassium Sorbate, Sodium Benzoate, Caramel, Cinnamomum Camphora (Camphor) Wood Oil, Limonene, Mentha Arvensis Leaf Oil, Tocopherol, Xanthan Gum, Caprylyl Glycol, Citrus Aurantium Dulcis (Orange) Oil, Fragrance (Parfum), Tephrosia Purpurea Seed Extract, Vitis Vinifera (Grape) Seed Oil, Menthol, Eugenia Caryophyllus (Clove) Leaf Oil, Sodium Hydroxide, Glyceryl Caprylate, Lactic Acid/Glycolic Acid Copolymer, Phenylpropanol, Palmitoyl Tetrapeptide-50, Polyvinyl Alcohol, Heptapeptide-15 Palmitate.

MADE IN ENGLAND

BRITISH Manufactured for ELEMIS Ltd

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BRAND US T: +1855 2 353647

69260



ULTIMATE PRO-COLLAGEN DAY AND NIGHT DUO

avobenzone, octinoxate, and octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:659 12-008
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:659 12-008-01	1 in 1 CONTAINER	09/01/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CONTAINER	50 g
Part 2	1 CONTAINER	50 g

Part 1 of 2

PRO-COLLAGEN OVERNIGHT MATRIX

lotions, oils, powders, and creams soap

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	CORN OIL (UNII: 8470G57WFM)	
INGR	Propanediol (UNII: 5965N8W85T)	
INGR	DOCOSANOL (UNII: 9G10E216XY)	
INGR	Squalane (UNII: GW89575KF9)	
INGR	Butylene Glycol (UNII: 3XUS85K0RA)	
INGR	OCTYLDODECANOL (UNII: 461N1O614Y)	
INGR	Dicaprylyl Carbonate (UNII: 609A3V1SUA)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	Phenoxyethanol (UNII: HIE492ZZ3T)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	Beheneth-25 (UNII: 0G17KJ5M7P)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	DUNALIELLA SALINA (UNII: F4O1DKI9A6)	
INGR	Rhizobian Gum (UNII: 0XNZ14VU7K)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	Dehydroacetic Acid (UNII: 2KAG279R6R)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	LAVANDIN OIL (UNII: 9RES347CKG)	
INGR	Pelargonium Graveolens Flower Oil (UNII: 3K0J1S7QGC)	
INGR	PADINA PAVONICA (UNII: 177U06NHZI)	
INGR	Geraniol (UNII: L837108USY)	
INGR	EUCALYPTUS OIL (UNII: 2R040NI662)	
INGR	Chlorphenesin (UNII: I670DAL4SZ)	
INGR	CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	Potassium Sorbate (UNII: 1VPU26JZZ4)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Caramel (UNII: T9D99G2B1R)	
INGR	CAMPHOR LEAF OIL (UNII: 51D0RGY52V)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	

INGR	MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	
INGR	Tocopherol (UNII: R0ZB2556P8)	
INGR	Xanthan Gum (UNII: TTV12P4NEE)	
INGR	Caprylyl Glycol (UNII: 00YIU5438U)	
INGR	ORANGE OIL (UNII: AKN3KSD11B)	
INGR	TEPHROSIA PURPUREA SEED (UNII: 01KT5NC1TC)	
INGR	GRAPE SEED OIL (UNII: 930MLC8XGG)	
INGR	MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
INGR	CLOVE LEAF OIL (UNII: VCA5491KVF)	
INGR	Sodium Hydroxide (UNII: 55X04QC32I)	
INGR	GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
INGR	Phenylpropanol (UNII: 0F897O3O4M)	
INGR	POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		50 g in 1 CONTAINER; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		09/01/2019	

Part 2 of 2

PRO-COLLAGEN MARINE SPF 30
avobenzene, octinoxate, and octocrylene cream

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	10 mg in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	10 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
Isononyl Isononanoate (UNII: S4V5BS6GCX)
Dicaprylyl Carbonate (UNII: 609A3V1SUA)
Dimethicone (UNII: 92RU3N3Y1O)
Phenoxyethanol (UNII: HIE492ZZ3T)
Butylene Glycol (UNII: 3XUS85K0RA)
Cetyl Alcohol (UNII: 936JST6JCN)
Hydroxyacetophenone (UNII: G1L3HT4CMH)
Stearic Acid (UNII: 4ELV7Z65AP)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
Coco-Caprylate (UNII: 4828G836N6)
Xanthan Gum (UNII: TTV12P4NEE)
Chlorphenesin (UNII: I670DAL4SZ)
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
Tocopherol (UNII: R0ZB2556P8)
SHEA BUTTER (UNII: K49155WL9Y)
CARROT (UNII: L56Z1JK48B)
WHEAT GERM OIL (UNII: 14C97E680P)
CHLORELLA VULGARIS (UNII: RYQ4R60M02)
PADINA PAVONICA (UNII: 177U06NHZ1)
Sodium Dehydroacetate (UNII: 8W46YN971G)
Polysorbate 20 (UNII: 7T1F30V5YH)
Sorbitan Isostearate (UNII: 01S2G2C1E4)
GINKGO (UNII: 19FUJ2C58T)
PORPHYRIDIUM PURPUREUM (UNII: K2P8K2558N)
ACACIA DECURRENS FLOWER (UNII: 8PHF3LSM61)
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)
Sodium Benzoate (UNII: OJ245FE5EU)
Potassium Sorbate (UNII: 1VPU26JZZ4)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		50 g in 1 CONTAINER; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	09/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	09/01/2019	

