

**PRO-COLLAGEN PERFECT 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.

PRO-COLLAGEN PERFECT DUO

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 Carton

The Pro-Collagen Perfect Duo

Pro-Collagen Marine Cream SPF 30

Broad Spectrum SPF 30 | Sunscreen

Pro-Collagen Night Cream

ELEMIS

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



Morning to Evening Hydration Heroes

The Pro-Collagen Perfect Duo



Hydrating night cream

ELEMIS
PRO-COLLAGEN
NIGHT CREAM

Broad Spectrum SPF 30 | Sunscreen

ELEMIS
PRO-COLLAGEN
MARINE CREAM SPF 30

SPECIAL DELIVERY

ELEMIS



PRO-COLLAGEN PERFECT DUO

avobenzone, octinoxate, and octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65912-010
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65912-010-01	1 in 1 BOX	09/01/2023	

Quantity of Parts

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

Part 1 of 2

PRO-COLLAGEN NIGHT CREAM

lotions, oils, powders, and creams cream

Product Information

Route of Administration

TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	LAURYL LAURATE (UNII: GPW77G0937)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
INGR	PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
INGR	JOJOBA OIL (UNII: 724GKU717M)	
INGR	STARCH, RICE (UNII: 4DGK8B7I3S)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
INGR	CHLORPHENESIN (UNII: I670DAL4SZ)	
INGR	SESAME OIL (UNII: QX10HYY4QV)	
INGR	WHEAT GERM OIL (UNII: 14C97E680P)	
INGR	AVOCADO OIL (UNII: 6VNO72PFC1)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
INGR	OLIVE OIL (UNII: 6UYK2W1W1E)	
INGR	PADINA PAVONICA (UNII: 177U06NHZ1)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	PHYMATOLITHON CALCAREUM (UNII: 6j1M3WA0ZK)	
INGR	MIMOSA TENUIFLORA BARK (UNII: 515MQE449I)	
INGR	MANNITOL (UNII: 3OWL53L36A)	
INGR	TOCOPHEROL (UNII: ROZB2556P8)	
INGR	SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
INGR	MALIC ACID (UNII: 817L1N4CKP)	
INGR	DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	ZINC SULFATE, UNSPECIFIED FORM (UNII: 89DS0H96TB)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	HEXAPEPTIDE-9 (UNII: L25414IE41)	
INGR	GERANIOL (UNII: L837108USY)	
INGR	LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
INGR	GLYCERYL ACRYLATE/ACRYLIC ACID COPOLYMER (30/70) (UNII: ...)	

INGR

GLYCERYL ACRYLATE/ACRYLIC ACID COPOLYMER (300000 CP AT 2%) (UNII: MEA9KH24QG)

Product Characteristics

color	white	C48325
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		50 mL 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		09/01/2023	

Part 2 of 2**PRO-COLLAGEN MARINE BROAD SPECTRUM SPF 30**

avobenzene, octinoxate, and octocrylene cream

Product Information

Item Code (Source)	NDC:65912-001
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Route of Administration	TOPICAL
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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: 3XUS85KORA)
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: K49I55WL9Y)
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)
GLYCERYL ACRYLATE/ACRYLIC ACID COPOLYMER (300000 CP AT 2%) (UNII: MEA9KH24QG)
POLYACRYLATE-13 (UNII: FS2D4T67EA)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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	09/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/01/2023	

Labeler - Elemis Ltd. (399838895)

Revised: 4/2023

Elemis Ltd.