

## **GIFT OF PRO-COLLAGEN ICONS- 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.*

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**GIFT OF PRO-COLLAGEN ICONS**

### ***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**

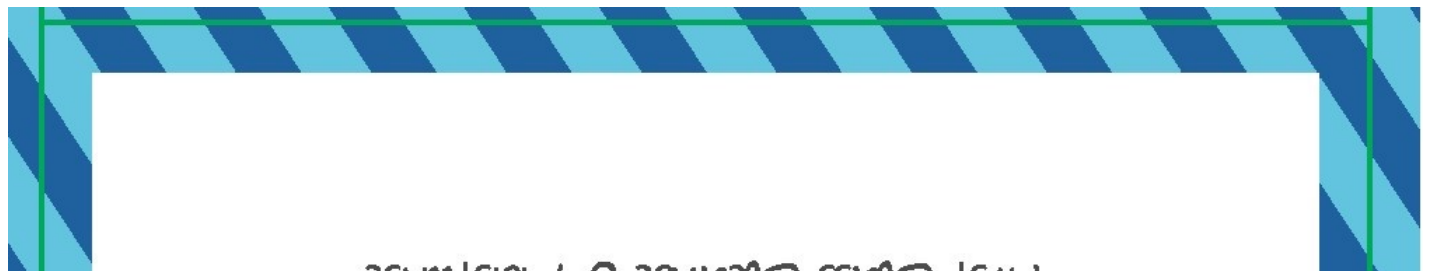
The Gift of Pro-Collagen Icons

Pro-Collagen Marine Cream SPF 30

Broad Spectrum SPF 30 | Sunscreen  
NET WT. 2x 50ml e 1.6 US fl. oz.

Pro-Collagen Cleansing Balm

NET WT./ Poids Net 50g e 1.7 oz.



*First Class Noano St Maistivico*

# The Gift of Pro-Collagen Icons



SPECIAL DELIVERY



**GIFT OF PRO-COLLAGEN ICONS**

avobenzone, octinoxate, and octocrylene kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65912-011
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65912-011-01	1 in 1 BOX	09/01/2023	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 CONTAINER	50 g
<b>Part 2</b>	1 CONTAINER	50 g

**Part 1 of 2**

**PRO-COLLAGEN CLEANSING BALM**

cleansing (cold creams, cleansing lotions, liquids, and pads) paste

**Product Information**

<b>Route of Administration</b>	TOPICAL
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## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
INGR	<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
INGR	<b>CAPRYLOCAPROYL POLYOXYLGLYCERIDES 6</b> (UNII: GO50W2HWO8)	
INGR	<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
INGR	<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
INGR	<b>PEG-60 ALMOND GLYCERIDES</b> (UNII: 4Y0E651N0F)	
INGR	<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
INGR	<b>OAT KERNEL OIL</b> (UNII: 3UVP41R77R)	
INGR	<b>WHEAT GERM OIL</b> (UNII: 14C97E680P)	
INGR	<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
INGR	<b>ORANGE PEEL WAX</b> (UNII: 0U715N387C)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
INGR	<b>PADINA PAVONICA</b> (UNII: 177U06NHZI)	
INGR	<b>BORAGE SEED OIL</b> (UNII: F8XAG1755S)	
INGR	<b>LAVENDER OIL</b> (UNII: ZBP1YXWOH8)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
INGR	<b>ACACIA DECURRENS FLOWER WAX</b> (UNII: AU6XZE9IY9)	
INGR	<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
INGR	<b>ROSA MULTIFLORA FLOWER WAX</b> (UNII: VU148CEP2J)	
INGR	<b>LAVANDIN OIL</b> (UNII: 9RES347CKG)	
INGR	<b>PELARGONIUM GRAVEOLENS FLOWER OIL</b> (UNII: 3K0J1S7QGC)	
INGR	<b>GERANIOL</b> (UNII: L837108USY)	
INGR	<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
INGR	<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
INGR	<b>CHAMAEMELUM NOBILE FLOWER OIL</b> (UNII: UB27587839)	
INGR	<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
INGR	<b>MENTHA ARVENSIS LEAF OIL</b> (UNII: 1AEY1M553N)	
INGR	<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
INGR	<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
INGR	<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
INGR	<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
INGR	<b>CLOVE LEAF OIL</b> (UNII: VCA5491KVF)	
INGR	<b>CITRAL</b> (UNII: T7EU0O9VPP)	
INGR	<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
INGR	<b>PEG-8 BEESWAX</b> (UNII: 3C1QUF1TIR)	
INGR	<b>SAMBUCUS NIGRA FLOWER OIL</b> (UNII: Q35633V53D)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		50 g in 1 CONTAINER; Type 0: Not a Combination Product		

## 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

avobenzone, octinoxate, and octocrylene cream

#### Product Information

Item Code (Source)	NDC:65912-001
Route of Administration	TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 mg in 1 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CARROT</b> (UNII: L56Z1JK48B)	
<b>WHEAT GERM OIL</b> (UNII: 14C97E680P)	

<b>CHLORELLA VULGARIS</b> (UNII: RYQ4R60M02)
<b>PADINA PAVONICA</b> (UNII: 177U06NHZI)
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)
<b>GINKGO</b> (UNII: 19FUJ2C58T)
<b>PORPHYRIDIUM PURPUREUM</b> (UNII: K2P8K2558N)
<b>ACACIA DECURRENS FLOWER</b> (UNII: 8PHF3LSM61)
<b>ROSA CENTIFOLIA FLOWER</b> (UNII: CS4TE8FF7O)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>POLYACRYLATE-13</b> (UNII: FS2D4T67EA)
<b>GLYCERYL ACRYLATE/ACRYLIC ACID COPOLYMER (300000 CP AT 2%)</b> (UNII: MEA9KH24QG)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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)

**Registrant** - Elemis Ltd. (399838895)