

**DAILY DEFENCE SUNSCREEN BROAD SPECTRUM SPF30- octinoxate, octisalate, avobenzone, and octocrylene cream**  
**ZELENS Limited**

*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.*

-----  
**DAILY DEFENCE SUNSCREEN Broad Spectrum SPF30**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3%	Sunscreen
Octinoxate 7.4%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 2.7%	Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

**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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours

**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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

**Other information**

- protect this product from excessive heat and direct sun
- you may report a serious adverse reaction to this product to: Report Reaction, LLC PO Box 22 Plainsboro, NJ 08536-0222

**Inactive ingredients**

Water, Cyclohexasiloxane, Glycerin, Butylene Glycol, Butyloctyl Salicylate, Isononyl Isononanoate, Glyceryl Stearate, PEG-100 Stearate, Dimethicone, Micrococcus Lysate, Perilla Frutescens Leaf Extract, Sodium Hylauronate, Glutamylamidoethyl Imidazole, Ascorbyl Tetraisopalmitate, Tocopheryl Acetate, Camellia Sinensis Leaf Extract, Centella Asiatica Extract, Echinacea Angustifolia Leaf Extract, Ginkgo Biloba Leaf Extract, Pinus Strobus Bark Extract, Lecithin, Silica, Hydrogenated Palm Glycerides, Cyclopentasiloxane, PVP, Potassium Cetyl Phosphate, Sorbitol, Cetearth-20, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Polyacrylate, Fragrance, Linalool, Sorbic Acid, Chlorphenesin, Phenoxyethanol, BHT, Sodium Hydroxide, Disodium EDTA

**PRINCIPAL DISPLAY PANEL - 50 mL Tube Box****zelens****dr marko lens****Daily Defence****SUNSCREEN****BROAD SPECTRUM SPF 30****High Protection****50 mL / 1.7 Fl.Oz.**



### Drug Facts (continued)

#### Inactive ingredients

Water, Cyclohexasiloxane, Glycerin, Butylene Glycol, Butyloctyl Salicylate, Isononyl Isononanoate, Glyceryl Stearate, PEG-100 Stearate, Dimethicone, Micrococcus Lysate, Perilla Frutescens Leaf Extract, Sodium Hyaluronate, Glutamylmethylimidazole, Ascorbyl Tetraisopalmitate, Tocopheryl Acetate, Camellia Sinensis Leaf Extract, Centella Asiatica Extract, Echinacea Angustifolia Leaf Extract, Ginkgo Biloba Leaf Extract, Pinus Strobus Bark Extract, Leothlin, Silica, Hydrogenated Palm Glycerides, Cyclopentasiloxane, PVP, Potassium Cetyl Phosphate, Sorbitol, Ceteareth-20, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Sodium Polyacrylate, Fragrance, Linalool, Sorbic Acid, Chlorphenesin, Phenoxethanol, BHT, Sodium Hydroxide, Disodium EDTA

**zelens**  
dr marko lens

### Daily Defence

SUNSCREEN  
BROAD SPECTRUM SPF 30

High Protection

Ultimate, velvet-touch sun cream formulated using novel micro-encapsulation technology to provide daily broad-spectrum protection against UVA and UVB rays. Enriched with powerful antioxidants this sunscreen reduces free radical formation and helps prevent sun damage. Reinforces the skin's natural barrier and combats signs of premature skin aging. Leaves skin protected, moisturized and comfortable. Oil-free. Dermatologist tested. Hypoallergenic.

Apply in the morning to clean face and neck. If used with other skincare, use as a last step in regimen. Can be used alone or under make up.

50 mL / 1.7 Fl.Oz.

Made in Italy

Zelens Ltd, 152 Grosvenor Road  
London SW1V 3JL, UK  
www.zelens.com



### Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Octinoxate 7.4%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 2.7%	Sunscreen

#### Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

#### Warnings

##### For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes.

Fluse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours

**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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

#### Other information

- protect this product from excessive heat and direct sun
- you may report a serious adverse reaction to this product to: Report Reaction, LLC  
PO Box 22 Plainsboro, NJ 08536-0222

CONTINUE ➔



# DAILY DEFENCE SUNSCREEN BROAD SPECTRUM SPF30

octinoxate, octisalate, avobenzone, and octocrylene cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63712-123
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	74 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ECHINACEA ANGUSTIFOLIA LEAF (UNII: FS7G8S6PJ8)	
GINKGO (UNII: 19FUJ2C58T)	
PINUS STROBUS BARK (UNII: 8PJ4761097)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SORBITOL (UNII: 506T60A25R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
SORBIC ACID (UNII: X045WJ989B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63712-123-01	1 in 1 BOX	06/02/2014	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/02/2014	

**Labeler** - ZELENS Limited (217149018)

Establishment			
Name	Address	ID/FEI	Business Operations
Originitalia		441072253	manufacture(63712-123)