

**ZELENS DAILY DEFENCE MINERAL SUNSCREEN SPF 30- zinc oxide 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.*

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**Zelens Daily Defence Mineral Sunscreen SPF 30**

**Drug Facts**

**Active ingredients**

Zinc Oxide 20%

**Purpose**

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 at least every 2 hours

- use a water resistant sunscreen if swimming or sweating

**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 611 Pompton Plains, NJ 07444

### **Inactive ingredients**

Aqua (Water), Caprylic/Capric Triglyceride, Propylheptyl Caprylate, Glycerin, Butyloctyl Salicylate, Lauryl Lactate, Propanediol, Lauryl Glucoside, Polyglyceryl-2 Dipolyhydroxystearate, Cetearyl Alcohol, Hydrogenated Vegetable Oil, Alpha-glucan Oligosaccharide, Lactobacillus, Lecithin, Dimethicone, Acetyl Hexapeptide-1 Perilla Frutescens Leaf Extract, Camellia Sinensis Leaf Extract, Centella Asiatica Leaf Extract, Malpighia Glabra (Acerola) Fruit Extract, Ginkgo Biloba Leaf Extract, Punica Granatum Fruit Extract, Haematococcus Pluvialis Extract, Pongamia Pinnata Seed Extract, Dunaliella Salina Extract, Pongamia Glabra Seed Oil, Diisopropyl Sebacate, Benzyl Alcohol, Isopropyl Palmitate, Xanthan Gum, Propylene Glycol Dicaprylate/dicaprate, Tocopherol, Sodium Stearoyl Glutamate, C12-15 Alkyl Benzoate, Diisopropyl Adipate, Dehydroacetic Acid, Sodium Dehydroacetate, Polymnia Sonchifolia Root Juice, Maltodextrin, Sorbitol, Citric Acid, Sodium Benzoate, Potassium Sorbate.

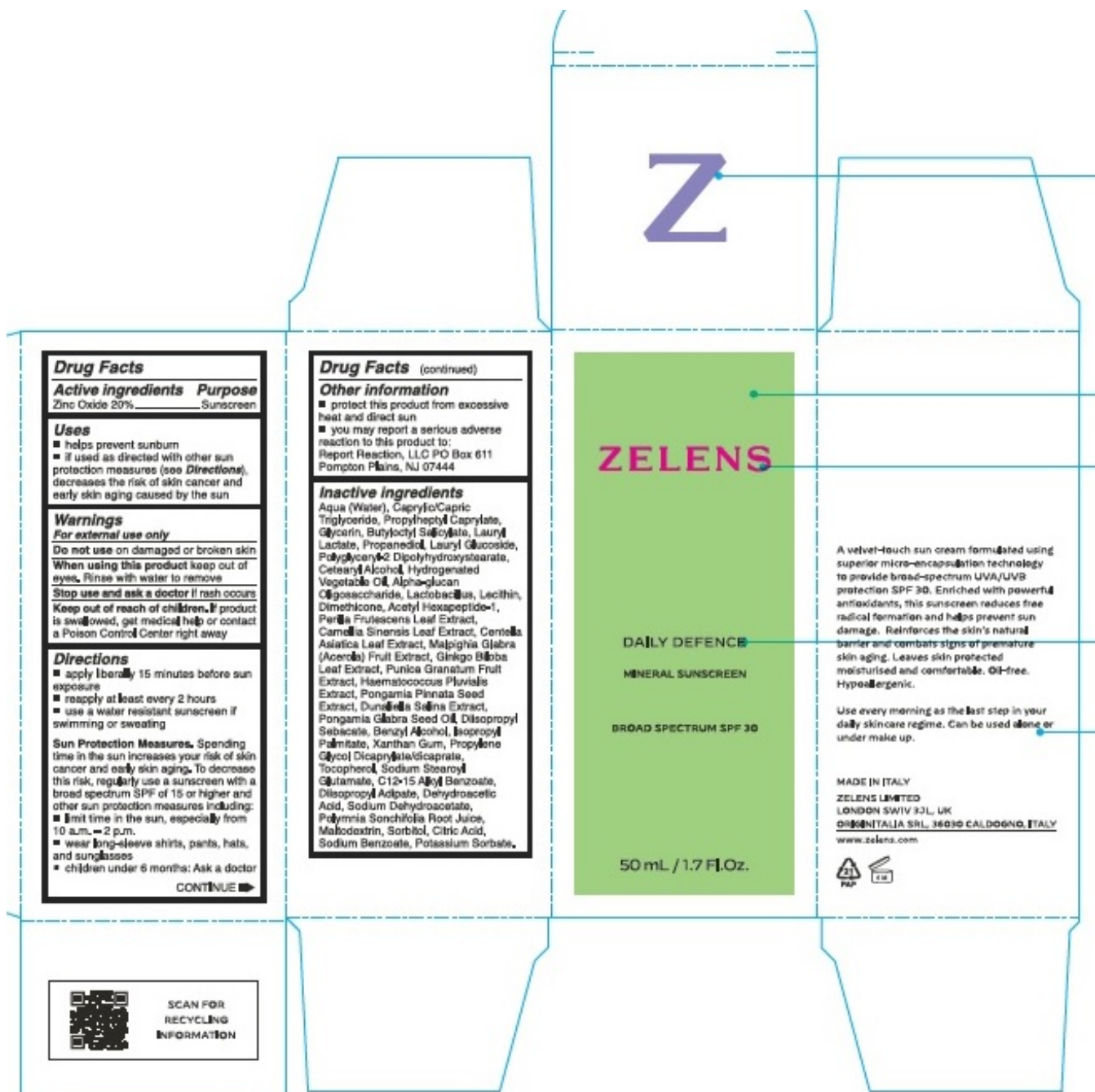
### **Company Information**

ZELENS LIMITED

LONDON SW1V 3JL, UK

[www.zelens.com](http://www.zelens.com)

### **Product Packaging**



## ZELENS DAILY DEFENCE MINERAL SUNSCREEN SPF 30

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63712-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PONGAMIA PINNATA SEED</b> (UNII: C2BRV53B1V)	
<b>LAURYL LACTATE</b> (UNII: G5SU0BFK7O)	
<b>DUNALIELLA SALINA</b> (UNII: F4O1DKI9A6)	
<b>MALPIGHIA GLABRA FRUIT</b> (UNII: B94O42LA9M)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>ACETYL HEXAPEPTIDE-1</b> (UNII: 49ZWR266MZ)	
<b>POMEGRANATE</b> (UNII: 56687D1Z4D)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>CENTELLA ASIATICA LEAF</b> (UNII: 6810070TYD)	
<b>GINKGO</b> (UNII: 19FUJ2C58T)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: O4446S9CRA)	
<b>PROPYLHEPTYL CAPRYLATE</b> (UNII: 991Z19V2OD)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DIISOPROPYL ADIPATE</b> (UNII: P7E6YFV72X)	
<b>.ALPHA.-GLUCAN OLIGOSACCHARIDE</b> (UNII: S95658MI3W)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE</b> (UNII: 9229XJ4V12)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PERILLA FRUTESCENS LEAF</b> (UNII: T4L5881Y68)	
<b>HAEMATOCOCCUS PLUVIALIS</b> (UNII: 31T0FF0472)	
<b>KARUM SEED OIL</b> (UNII: 62160PU6FJ)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>SMALLANTHUS SONCHIFOLIUS ROOT JUICE</b> (UNII: M9S7HX36CT)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:63712-001-01	1 in 1 CARTON	04/01/2023	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:63712-001-02	2 mL in 1 PACKET; Type 0: Not a Combination Product	05/19/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	04/01/2023	

**Labeler** - Zelens Limited (217149018)

Revised: 5/2023

Zelens Limited