

**ELEVATED ULTIMATE SUN DEFENSE BROADSPECTRUM SPF 30 (UVA/UVB)
SUNSCREEN- titanium dioxide and zinc oxide liquid
Elevated Dermatology and Skin**

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.

**Elevated Ultimate Sun Defense Broad Spectrum SPF30 (UVA/UVB) Sunscreen
DRUG FACTS:**

ACTIVE INGREDIENTS

Titanium Dioxide 7.2%, Zinc Oxide 4.0%.

Purpose

Sunscreen

USES

Helps prevent sunburn.

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.

DIRECTIONS

Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For 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.

INACTIVE INGREDIENTS

Water (Aqua), Butyloctyl Salicylate, Glycerin, Dimethicone, Caprylic/Capric Triglyceride, Propanediol, Polyglyceryl-10 Oleate, Coco-Caprylate/Caprates, Styrene/Acrylates Copolymer, Polyhydroxystearic Acid, Rosa Damascena Flower Water, Phenoxyethanol, Aluminum Stearate, Carthamus Tinctorius Oleosomes, Alumina, Butylene Glycol,

Polyglyceryl-2 Caprate, Microcrystalline Cellulose, Potassium Cetyl Phosphate, Polyglyceryl-3 Polyricinoleate, Simmondsia Chinensis (Jojoba) Seed Oil, Stearic Acid, Sucrose Stearate, Marrubium Vulgare Meristem Cell Culture, Polyglyceryl-3 Diisostearate, Triethoxycaprylylsilane, Ethylhexylglycerin, Camellia Sinensis Leaf Extract, Cellulose Gum, Glyceryl Caprylate, Squalane, Carbomer, Polysorbate 20, Aspalathus Linearis Extract, Palmitoyl Tripeptide-1, Xanthan Gum, Palmitoyl Tetrapeptide-7, Polygonum Aviculare Extract.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

**Elevated Ultimate
Sun Defense
BroadSpectrum SPF 30
(UVA/UVB) Sunscreen
1.75 fl oz (50 ml)**



Elevated Ultimate
Sun Defense
Broad Spectrum SPF30
(UVA/UVB) Sunscreen

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USES: Helps prevent sunburn.

WARNINGS:

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Distributed By:
Elevated Dermatology and Skin
Parker, CO 80138
www.elevatedderm.com
Made in USA

*the above image is a digital representation, actual products may differ slightly.

Elevated Ultimate

Sun Defense
BroadSpectrum SPF 30
(UVA/UVB) Sunscreen

ELEVATED ULTIMATE SUN DEFENSE BROADSPECTRUM SPF 30 (UVA/UVB) SUNSCREEN

titanium dioxide and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81688-2750
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.2 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPANEDIOL (UNII: 5965N8W85T)	
POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
JOJOBA OIL (UNII: 724GKU717M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE STEARATE (UNII: 274KW0050M)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	

SQUALANE (UNII: GW89575KF9)

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)

POLYSORBATE 20 (UNII: 7T1F30V5YH)

PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)

XANTHAN GUM (UNII: TTV12P4NEE)

PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)

POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81688-2750-3	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2021	

Labeler - Elevated Dermatology and Skin (094623214)

Revised: 4/2021

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