

ANNA LOTAN PREMIUM BB CREAM SPF46 PALE BEIGE- titanium dioxide, octinoxate cream
Anna Lotan 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.

anna lotan Premium BB Cream SPF46 Pale Beige

Drug Facts

Active Ingredients

Titanium Dioxide 16%
Octinoxate 6.99%

Purpose:

Sunscreen

Uses

- Helps to prevent sunburn
- If used as directed with other sun protective 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. If contact occurs rinse thoroughly 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 protection measures including: • Limit

time in sun from 10 a.m.- 2 p.m. • Wear long-sleeve shirts, pants, hats and sunglasses.
• Children under 6 months: Ask a doctor.

Inactive Ingredients

Water, Caprylic/Capric Triglyceride, Dicaprylyl Ether, Cyclopentasiloxane, Talc, Cetyl PEG/PPG-10/1 Dimethicone, Dimethicone, Cyclohexasiloxane, Cetearyl Ethylhexanoate, Methyl Methacrylate Crosspolymer, Dipalmitoyl Hydroxyproline, Myristyl Myristate, Phenoxyethanol, Stearalkonium Hectorite, Microcrystalline Wax, Sodium Chloride, Paraffin, Polysilicone-11, Propylene Carbonate, Ethylhexylglycerin, Tocopherol, Helianthus Annuus (Sunflower) Seed Oil, BHT, Iron Oxides (CI 77491, CI 77492, CI 77499).

Questions or comments

info@annalotanusa.com

Tel: **(781) 281 0954**

PRO

SUN Select

Pale Beige **1**

for normal/dry skin

A multi-functional formula that serves as an optimal day care for normal to dry skin types, giving long lasting coverage, moisturisation and a wrinkle-relaxing effect.

- A concentrated formula. A little will go a long way.
- Applied in the morning, still looks great at the end of a busy day.
- Formulated as a W/O emulsion that naturally repels water. However, care should be taken when regularly used on skin with enlarged pores!
- Excellent spreading and adherence on the skin, offering optimal coverage for discolorations, including under eye dark circles!
- A targeted combination of the amino acid proline and palm oil enhances skin penetration and provides a “plumping” anti-wrinkle effect, making it ideal for dry, mature skin.
- Enriched with emollient oils that smooth the skin and prevent the typical accentuation of fine lines common with many concealing makeup products.
- Vitamin E acts as antioxidant minimizing free radical damage.
- Premium BB Cream combines concealing opacity with a light translucent veil which becomes apparent once the cream is fully absorbed. This veil allows your natural skin tone to shine through.

Directions: Using sparingly, carefully spread the cream with fingertip massage to form an even layer on face, under eye area or wherever required until a smooth, even coverage is obtained.

US Distribution: Anna Lotan USA Inc.
16 Wheeling Ave, Woburn, MA 01801
www.annalotanusa.com

Packaging

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Pale Beige 1

Premium
BB Cream SPF 46
for normal/dry skin

30 ml. 1 fl. oz

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BOX3041PUS1

ANNA LOTAN PREMIUM BB CREAM SPF46 PALE BEIGE

titanium dioxide, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76446-041
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	16 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.99 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
TALC (UNII: 7SEV7J4R1U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARALKONIUM HECTORITE (UNII: OLX698AH5P)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PARAFFIN (UNII: I9O0E3H2ZE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76446-041-30	1 in 1 CARTON	09/15/2023	
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/15/2023	

Labeler - Anna Lotan Ltd (600458368)

Revised: 9/2023

Anna Lotan Ltd