

ANNA LOTAN LIGHTLY TINTED MINERAL DAY CREAM BROAD SPECTRUM SPF 30- titanium dioxide, zinc oxide 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 PRO SUN Select Lightly Tinted Mineral Day Cream Broad Spectrum SPF 30

Drug Facts

Active Ingredients

Titanium Dioxide 7.75%

Zinc Oxide 10.0%

Purpose:

Sunscreen

Uses

- **helps 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. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

Directions

- apply to all skin exposed to the sun
- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use water resistant sunscreen if swimming or sweating
- for children under 6 months: 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 sun from 10 a.m.- 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

water (aqua), caprylic/capric triglyceride, butyloctyl salicylate, glycerin, dimethicone, styrene/acrylates copolymer, coco-caprylate/caprate, aluminum stearate, carthamus tinctorius oleosomes, polyhydroxystearic acid, aloe barbadensis leaf juice, polygonum aviculare extract, tocopheryl acetate, perilla frutescens extract, vitis vinifera fruit cell extract, lepidium sativum sprout extract, squalane, cetearyl alcohol, isononyl isononanoate, coco-glucoside, pentylene glycol, behenyl alcohol, xanthan gum, triethoxycaprylylsilane, arachidyl glucoside, simmondsia chinensis (jojoba) seed oil, stearic acid, sucrose stearate, phenethyl alcohol, tetrahexyldecyl ascorbate, glyceryl caprylate, ethylene/propylene/styrene copolymer, sorbitan oleate, polyglyceryl-2 caprate, propanediol, alumina, arachidyl alcohol, iron oxides (CI 77492, CI 77491, CI 77499).

Questions or Comments?

(781) 281-0954

For all skin types

This lightly tinted daytime moisturizer provides broad spectrum protection based on **minerals alone** excluding chemical absorbers.

The formula is enriched with skin friendly, sustainable emollients which are easily absorbed by the skin while minimizing the white appearance common to mineral based sunscreens.

A wide range of free radical scavengers provides the **antioxidant protection** which is vital during exposure to UV light.

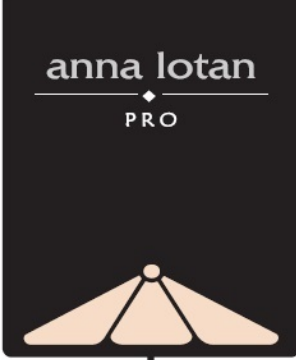




Vitamin E supported by a stable ester form of **Vitamin C** protects the skin's own lipids as well as the seed oils in the formula.

Extracts of **Garden Cress** sprouts and **Grapes** contribute their antioxidants to the water based part of the composition.

Distributed by: Anna Lotan USA Inc.
16 Wheeling Ave, Woburn, MA 01801

www.annalotanusa.com
info@annalotanusa.com

Packaging

Drug Facts	Drug Facts (continued)	 <p style="text-align: center;">SUN Select</p>	
Active Ingredients Purpose: Titanium Dioxide 7.75%..... } Sunscreen Zinc Oxide 10.0%..... }	Other information ■ protect the product in this container from excessive heat and direct sun		This lightly tinted daytime moisturizer provides broad spectrum protection based on minerals alone excluding chemical absorbers.
Uses ■ helps 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.	Inactive ingredients water (aqua), caprylic/capric triglyceride, butyloctyl salicylate, glycerin, dimethicone, styrene/acrylates copolymer, coco-caprylate/caprate, aluminum stearate, carthamus tinctorius oleosomes, polyhydroxystearic acid, aloe barbadensis leaf juice, polygonum aviculare extract, tocopheryl acetate, perilla frutescens extract, vitis vinifera fruit cell extract, lepidium sativum sprout extract, squalane, cetearyl alcohol, isononyl isonanoate, coco-glucoside, pentylene glycol, behenyl alcohol, xanthan gum, triethoxycaprylylsilane, arachidyl glucoside, simmondsia chinensis (jojoba) seed oil, stearic acid, sucrose stearate, phenethyl alcohol, tetrahexyldecyl ascorbate, glyceryl caprylate, ethylene/propylene/styrene copolymer, sorbitan oleate, polyglyceryl-2 caprate, propanediol, alumina, arachidyl alcohol, iron oxides (CI 77492, CI 77491, CI 77499).		The formula is enriched with skin friendly, sustainable emollients which are easily absorbed by the skin while minimizing the white appearance common to mineral based sunscreens.
Warnings For external use only.	Questions or Comments? (781) 281-0954		A wide range of free radical scavengers provides the antioxidant protection which is vital during exposure to UV light.
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.			Vitamin E supported by a stable ester form of Vitamin C protects the skin's own lipids as well as the seed oils in the formula.
Directions ■ apply to all skin exposed to the sun ■ apply liberally 15 minutes before sun exposure ■ reapply at least every 2 hours ■ use water resistant sunscreen if swimming or sweating ■ for children under 6 months: 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 sun from 10 a.m.- 2 p.m. ■ wear long-sleeved shirts, pants, hats and sunglasses		Extracts of Garden Cress sprouts and Grapes contribute their antioxidants to the water based part of the composition.	
		Lightly Tinted Mineral Day Cream Broad Spectrum SPF 30 For all skin types	
Distributed by: Anna Lotan USA Inc. 16 Wheeling Ave, Woburn, MA 01801 www.annalotanusa.com info@annalotanusa.com  8 50034 33801 9 		1.7 fl. oz. (50ml.)	

ANNA LOTAN LIGHTLY TINTED MINERAL DAY CREAM BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76446-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.75 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STYRENE/ACRYLAMIDE COPOLYMER (50000 MW) (UNII: 5Z4DPO246A)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)	
VITIS VINIFERA HIGH TANNIN CULTIVAR FRUIT CELL LYSATE (UNII: ZLW3M94UYA)	
GARDEN CRESS SPROUT (UNII: PWQ18YNR62)	
SQUALANE (UNII: GW89575KF9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DOCOSANOL (UNII: 9G1OE216XY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)	
JOJOBA OIL (UNII: 724GKU717M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE STEARATE (UNII: 274KW0050M)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76446-300-50	1 in 1 CARTON	05/25/2022	
1		50 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	part352	05/25/2022	

Labeler - Anna Lotan Ltd (600458368)

Revised: 5/2022

Anna Lotan Ltd