

**ROSEASE BY ANNA LOTAN GENTLE DAYTIME BROAD SPECTRUM SPF 30-  
octinoxate, 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.*

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**ROSEASE by Anna Lotan Gentle Daytime PROTECTIVE MOISTURIZER Broad  
Spectrum SPF 30**

**DRUG FACTS:**

**ACTIVE INGREDIENTS:**

Octinoxate 7.5%  
Zinc Oxide 10.0%

**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.

**Keep out of reach of children.**

**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 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 sun from 10 a.m.- 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.

### **INACTIVE INGREDIENTS:**

water (aqua), butyloctyl salicylate, glycerin, dimethicone, styrene/acrylates copolymer, coco-caprylate/caprate, caprylic/capric triglyceride, vp/eicosene copolymer, carthamus tinctorius oleosomes, elettaria cardamomum seed extract, aloe barbadensis leaf juice, tocopheryl acetate, perilla frutescens extract, pyrus malus (apple) fruit extract, rose extract, santalum album extract, camellia sinensis leaf extract, anthemis nobilis flower extract, cananga odorata flower extract, citrus aurantium dulcis (orange) peel extract, cucumis melo (melon) fruit extract, cucumis sativus fruit extract, jasminum officinale flower/leaf extract, lavandula angustifolia (lavender) flower / leaf / stem extract, rubus idaeus (raspberry) fruit extract, polygonum aviculare extract, vitis vinifera fruit cell extract, propanediol, cetearyl alcohol, pentylene glycol, arachidyl alcohol, polyhydroxystearic acid, cocoglucoside, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, behenyl alcohol, xanthan gum, triethoxycaprylylsilane, arachidyl glucoside, phenethyl alcohol, caprylyl glycol.

### **OTHER INFORMATION:**

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

### **QUESTIONS OR COMMENTS?**

(781) 281-0954

### **ENRICHED WITH BOTANICAL EXTRACTS**

### **EXCELLENT SKIN TOLERANCE**

### **FREE RADICAL PROTECTION**

For All Skin Types

**8**

### **DERMATOLOGICALLY TESTED**

TENDER LOVING CARE

NON-IRRITATING

THE ROSEASE TOOLKIT

Distributed by:

**Anna Lotan USA Inc.**

16 Wheeling Ave.

Woburn, MA 01801

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

### **Packaging**

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648P



# ROSEASE



Gentle Daytime  
**PROTECTIVE  
MOISTURIZER**

**Broad Spectrum  
SPF 30**

THE ROSEASE TOOLKIT



**ENRICHED WITH  
BOTANICAL EXTRACTS**

**EXCELLENT SKIN  
TOLERANCE**

**FREE RADICAL  
PROTECTION**

For All Skin Types



THE ROSEASE TOOLKIT



75 ml. e 2.5 fl. oz.

**ROSEASE BY ANNA LOTAN GENTLE DAYTIME BROAD SPECTRUM SPF 30**

octinoxate, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76446-648
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (50000 MW)</b> (UNII: 5Z4DPO246A)	
<b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>CARTHAMUS TINCTORIUS SEED OLEOSOMES</b> (UNII: 9S60Q72309)	
<b>CARDAMOM</b> (UNII: 8BC4CUT4JL)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PERILLA FRUTESCENS LEAF</b> (UNII: T4L5881Y68)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>ROSA CENTIFOLIA FLOWER</b> (UNII: CS4TE8FF7O)	
<b>SANDALWOOD</b> (UNII: 3641YW25N2)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CHAMAEMELUM NOBILE FLOWER</b> (UNII: O2T154T6OG)	
<b>CANANGA ODORATA FLOWER</b> (UNII: 76GTF6Z97M)	
<b>ORANGE PEEL</b> (UNII: T19T76XD44)	
<b>MUSKMELON</b> (UNII: ZV095H5633)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>JASMINUM OFFICINALE FLOWER</b> (UNII: 0Q8K841432)	
<b>LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP</b> (UNII: 9YT4B71U8P)	
<b>RASPBERRY</b> (UNII: 4N14V5R27W)	
<b>POLYGONUM AVICULARE TOP</b> (UNII: ZCD6009IUF)	
<b>VITIS VINIFERA HIGH TANNIN CULTIVAR FRUIT CELL LYSATE</b> (UNII: ZLW3M94UYA)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	

**HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)** (UNII: 86FQE96TZ4)

**DOCOSANOL** (UNII: 9G1OE216XY)

**XANTHAN GUM** (UNII: TTV12P4NEE)

**TRIETHOXYCAPRYLYLSILANE** (UNII: LDC331P08E)

**ARACHIDYL GLUCOSIDE** (UNII: 6JVW35JOOJ)

**PHENYLETHYL ALCOHOL** (UNII: ML9LGA7468)

**CAPRYLYL GLYCOL** (UNII: 00YIU5438U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76446-648-75	1 in 1 CARTON	05/25/2022	
1		75 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