

COMPLETE BEAUTY- octinoxate, zinc oxide lotion
American Sales Co

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.

Beauty Lotion SPF 15
909

Active ingredients

Octinoxate 6.0%

Zinc oxide 3.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the rise 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 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 value of 15 or higher and other sun protection measures including:

- limit the time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Other information

- protect the product from excessive heat and direct sun

Inactive ingredients

water, glycerin, isoheaxadecane, sodium acrylate/sodium acryloyldimethyl taurate copolymer, polysorbate 80, laureth-7, cyclopentasiloxane, cyclohexasiloxane, PEG/PPG-20/20 dimethicone, steareth-21, stearyl alcohol, Gossypium Herbaceum (cotton) seed oil, behenyl alcohol, cetyl alcohol, DMDM hydantoin, iodopropynyl butylcarbamate, fragrance, tocopheryl acetate, disodium EDTA, steareth-2, oleth-3 phosphate, ascorbic acid, panthenol

Complete Beauty lotion

100% Aino benzoic Acid (PABA)-Free

Dermatologist Tested

Light, Non-Greasy Formula

Non-Comedogenic (Won't Clog Pores)

Broad Spectrum SPF 15 Sunscreen

When used as directed, complete beauty lotion helps provide your skin with broad spectrum protection against premature skin damage from both UVA and UVB rays to help your skin stay younger looking.

ALL DAY MOISTURE - Formulated with antioxidant Vitamin E plus C and nourishing beauty moisture that absorbs quickly into skin and lasts all day to help your skin stay soft, smooth and beautiful.

DISTRIBUTED BY:

AMERICAN SALES CO.

4201 WALDEN AVE

LANCASTER, NY 14086

www.care1.info

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Quality Guaranteed or Your Money Back

909.005/909AE

Principal display Panel

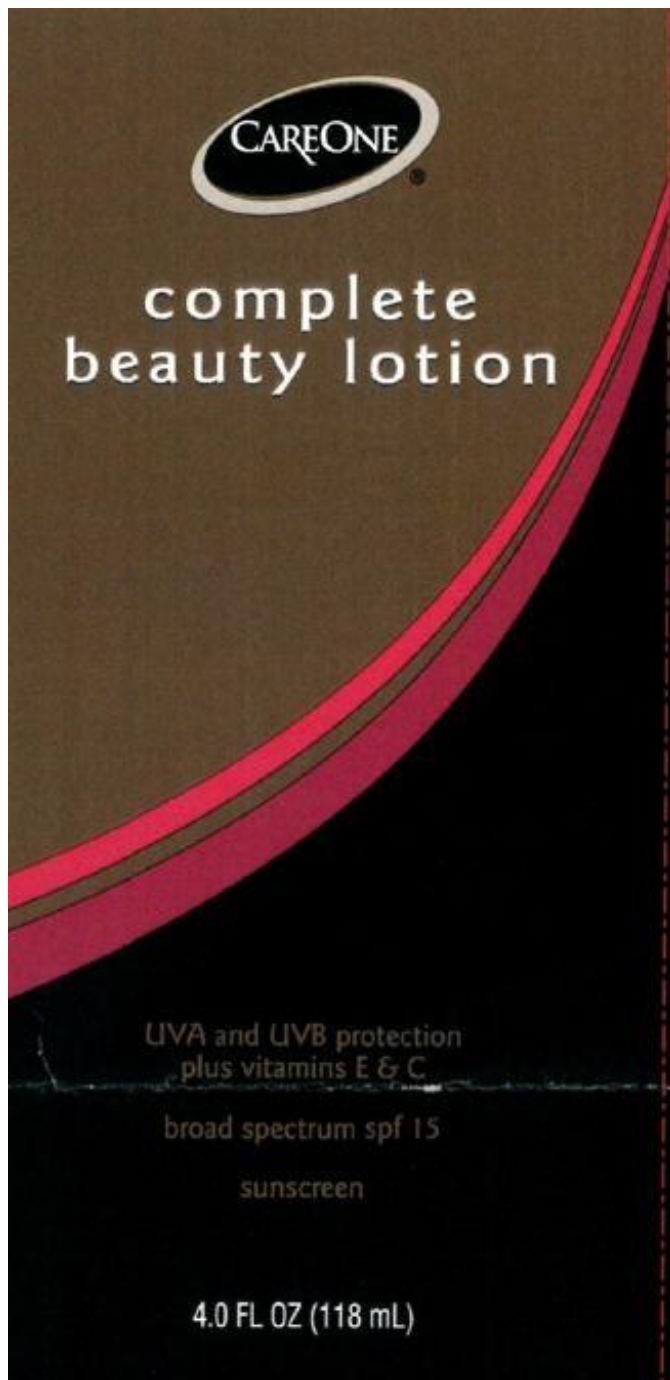
CAREONE

complete beauty lotion

UVA and UVB protection plus vitamin E + C

broad spectrum spf 15 sunscreen

4.0 fl oz (118 mL)



COMPLETE BEAUTY

octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-909
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	61.2 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	30.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LAURETH-7 (UNII: Z95S6G8201)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PEG/PPG-20/20 DIMETHICONE (UNII: BA94B7CK8K)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
LEVANT COTTONSEED OIL (UNII: N5CFT140R8)	
DOCOSANOL (UNII: 9G1OE216XY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARETH-2 (UNII: V56DFE46J5)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PANTHENOL (UNII: WV9CM0067Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-909-26	1 in 1 PACKAGE	01/13/2010	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/13/2010	

Labeler - American Sales Co (809183973)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
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Vi-Jon		790752542	manufacture(41520-909)
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Revised: 5/2020

American Sales Co