

COMPLETE BEAUTY- octinoxate, zinc oxide lotion
Wakefern Food Corporation

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.

Drug Facts

Extra back panel claims

Complete

beauty lotion

all day moisturizer

Broad Spectrum SPF 15

Sunscreen

ShopRite

Active ingredients

Active ingredients

Octinoxate 6.0%

Zinc Oxide 3.0%

Purpose

Purpose

Sunscreen

Use

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

Warnings

For external use only

Do not use

Do not use on damaged or broken skin

When using this product

When using this product keep out of eyes. rinse with water to remove

Stop use

Stop use and ask a doctor if rash occurs

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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 aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protections measures including:
- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-fleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

other information

Other information

- protect the product from excessive heat and direct sun

Inactive ingredients

Inactive ingredients water, glycerin, isohexadecan, polysorbate 80, sodium acrylate/acryloyldimethyl taurate copolymer, laureth-7, cyclopentasiloxane, PEG/PPG-20/20 dimethicone, steareth-21, stearyl alcohol, gossypium herbaceum (cotton) seed oil, behenyl alcohol, tocopheryl acetate, cetyl alcohol, DMDM hydantoin, itodpropynyl butylcarbamate, steareth-2, disodium EDTA, aloe barbadensis leaf extract, oleth-3 phosphate

Side Panel Claims

Broad spectrum SPF 15

Sunscreen

with vitaming E and aloe

Sensitive Skin

light and non-greasy lotion

ShopRite

Disclaimer

This product is not manufactured or distributed by Procter + Gamble, distributor or Olay Complete All Day Moisture Lotion SPF 15

Adverse Reactions Section

DISTRIBUTED BY

WAKEFERN FOOD CORPORATION

5000 RIVERSIDE DRIVE,

KEASBEY, NJ 08832

1-800-SHOPRITE

www.shoprite.com

principal display panel

Compare to Olay Complete All Day Moisture Lotion SPF 15

complete

beauty

lotion

all day

moisturizer

Broad Spectrum SPF 15

Sunscreen

with vitamin E and aloe

Sensitive Skin

light and non-greasy lotion

ShopRite

4 FL OZ (118 mL)



COMPLETE BEAUTY

octinoxate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-503
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X10UF1E)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)
LAURETH-7 (UNII: Z95S6G8201)
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)
PEG/PPG-20/20 DIMETHICONE (UNII: BA94B7CK8K)
STEARETH-21 (UNII: 53J3F32P58)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
LEVANT COTTONSEED OIL (UNII: N5CFT140R8)
DOCOSANOL (UNII: 9G1OE216XY)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CETYL ALCOHOL (UNII: 936JST6JCN)
DMDM HYDANTOIN (UNII: BYR0546TOW)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
STEARETH-2 (UNII: V56DFE46J5)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-503-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/09/2013	

Labeler - Wakefern Food Corporation (069722418)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(41190-503)