DAILY DEFENSE SPF 15 JAFRA- octinoxate, zinc oxide cream Jafra Cosmetics International Inc

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.

Time Protector Daily Defense Cream Broad Spectrum SPF 15

Active ingredients purpose

Octinoxate 7.5% Sunscreen

Zinc Oxide 3% Sunscreen

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.

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

Stop use and ask a doctor if rash occurs

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.

Directions

apply lliberally 15 minutes before sun exposure

use a water resistant sunscreen if swimming or sweating

reapply at least every 2 hours

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 the sun, especially from 10 a.m. - 2p.m.

wear long sleeve shirts, pants, hats, and sunglasses.

Water/Aqua, Gelatin, Retinyl Palmitate, Tridecyl Neopentanoate, Polyglyceryl-3 Methylglucose Distearate, Dimethicone, Glyceryl Stearate, Glycerin, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Triticum vulgare (Wheat) Germ Protein, Avena Sativa (Oat) Kernel Protein, Saccharide Isomerate, Glycine Soja (Soybean) Seed Extract, Ceramide 3, Propylene Glycol, Camellia Sinensis Leaf Extract, Panthenol, Ubiquinone, Chondrus Crispus (Carrageenan) Extract, Biosaccharide Gum-4, Chlorella Vulgaris extract, Phytosterol Isostearate, Allantoin, Ascorbyl Methylsilanol Pectinate, Tocopheryl Acetate, Lecithin, Caprylic/Capric Triglyceride, Diisopropyl Adipate, Trisodium EDTA, Diazolidnyl Urea, Methylparaben, Propylparaben.

Drug Facts

Active ingredients

Purpose

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IAFRA

Founded by Jan and Frank Day **SINCE 1956**

Made in Mexico for: JAFRA Cosmetics International, Inc. Westlake Village, CA 91361
Distributed in EU: JAFRA Cosmetics D-80636 Munich

www.JAFRA.com

Hecho en México para: Distribuidora Comercial JAFRA, S.A. de C.V.

Blvd. Adolfo López Mateos 515, Col. Tiacopac, México, D. F., 01040 JAFRA es Marca Registrada

LOS ANGELES - ZURICH - MUNICH MEXICO CITY - MILAN - MOSCOW



TIME PROTECTOR DAILY DEFENSE CREAM **BROAD SPECTRUM SPF 15**

WITH INTELLISHIELD

CONT. NET. 50 ml @ 1.7 FL OZ (US)

Drug Facts (continued)

Inactive ingredients
Water/Aqua, Gelatin, Retinyl Palmitate, Tridecyl Neopentanoate, Polyglyceryl-3 Methylglucose Distearate, Dimethicone, Glyceryl Stearate, Glycerin, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Triticum vulgare (Wheat) Germ Protein, Avena Sativa (Oat) Kernel Protein, Saccharide Isomerate, Glycine Soja (Soybean) Seed Extract, Ceramide 3, Propylene Glycol, Camellia Sinensis Leaf Extract, Panthenol, Ubiquinone, Chondrus Crispus (Carrageenan) Extract, Biosaccharide Gum-4, Chlorella Vulgaris Extract, Phytosterol Isostearate, Allantoin, Ascorbyl Methylsilanol Pectinate, Tocopheryl Acetate, Lecithin, Caprylic/Capric Triglyceride, Diisopropyl Adipate, Trisodium EDTA, Diazolidinyl Urea, Methylparaben, Propylparaben

Other information

protect this product from excessive heat and direct sun

Jafra Time Dynamics Time Dynamics Time Protector Daily Defense Cream Broad Spectrum SPF 15 with intellishield cont. Net. 50 ml 1.7 Fl Oz (US)

DAILY DEFENSE SPF 15 JAFRA

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-131
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
TRIDECYL NEO PENTANO ATE (UNII: 3Z8 H1DA7J5)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
WHEAT GERM (UNII: YR3G369F5A)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
CERAMIDE 3 (UNII: 4370 DF0 50 B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PANTHENOL (UNII: WV9CM0O67Z)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
ALLANTO IN (UNII: 344S277G0Z)	
ASCORBYL METHYLSILANOL PECTINATE (UNII: M3PF9237YC)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)	
EDETATE TRISODIUM (UNII: 420 IP9 21MB)	
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:68828-131-02	1 in 1 CARTON	05/30/2012	
1 NDC:68828-131-01	50 mL in 1 JAR; 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	05/30/2012	

Labeler - Jafra Cosmetics International Inc (041676479)

Registrant - Jafra Cosmetics International Inc (041676479)

Establishment			
Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture (68828-131)

Revised: 12/2018 Jafra Cosmetics International Inc