

DEFY TIME PROTECTOR MOISTURIZER BROAD SPECTRUM SPF 15 JAFRA TIME

DYNAMICS- octinoxate, zinc oxide cream

Jafra Cosmetics International

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.

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 liberally 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 of SPF 15 or higher and other sun protection measures including:

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

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

☐Inactive Ingredients

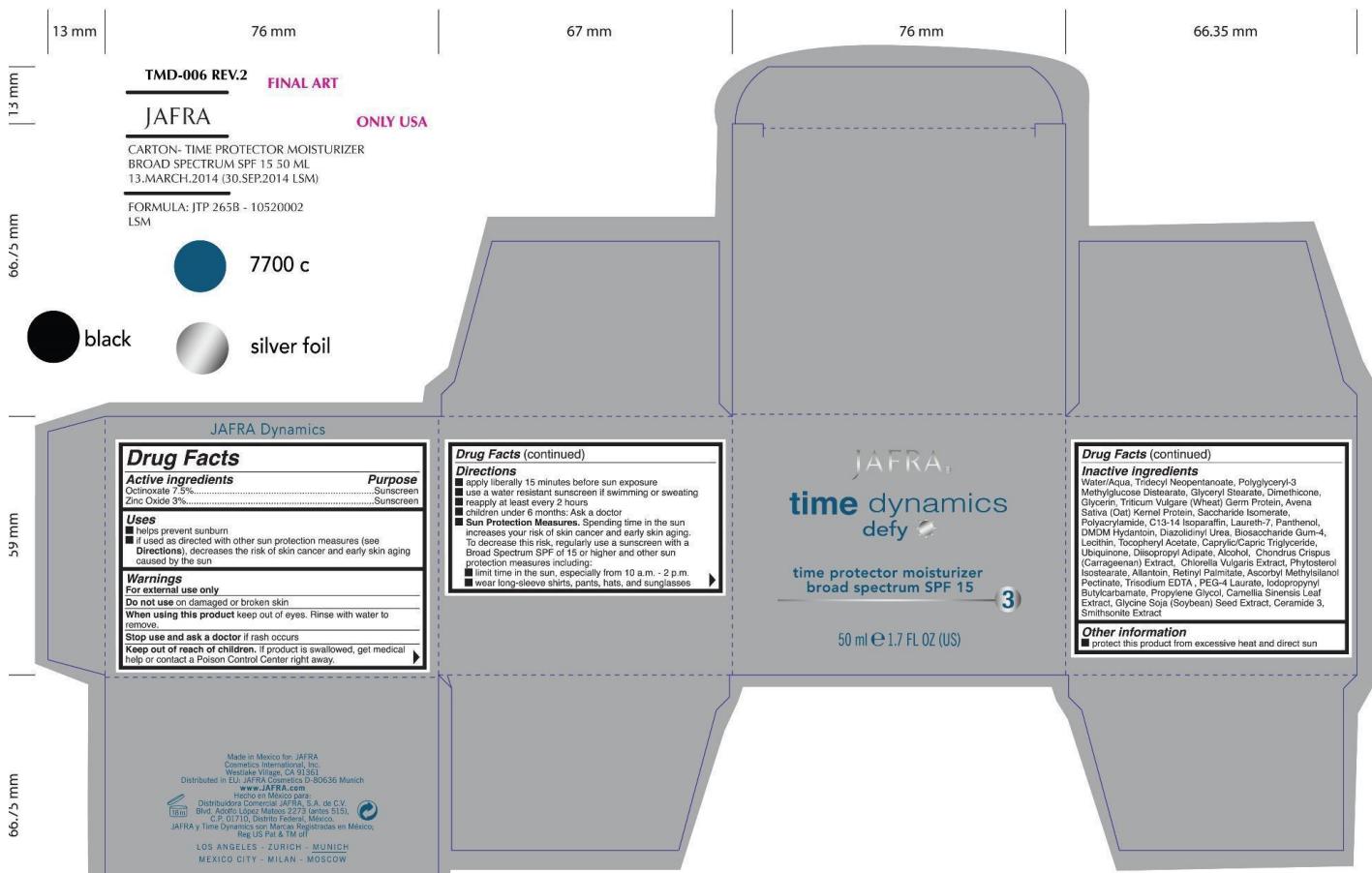
Water/Aqua, Tridecyl Neopentanoate, Polyglyceryl-3 Methylglucose Distearate, Glyceryl Stearate, Dimethicone, Glycerin, Triticum Vulgare (Wheat) Germ Protein, Avena Sativa (Oat) Kernel Protein, Saccharide Isomerate, Polyacrylamide, C13-14Isoparaffin, Laureth-7, Panthenol, DMDM Hydantoin, Diazolidinyl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

Jafra

time dynamics defy

Time protector Moisturizer broad spectrum SPF 15

50ml 1.7fl oz



DEFY TIME PROTECTOR MOISTURIZER BROAD SPECTRUM SPF 15 JAFRA TIME DYNAMICS

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-201
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: 059QF0K00R)	
TRIDECYL NEOPENTANOATE (UNII: 3Z8H1DA7J5)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

GLYCERIN (UNII: PDC6A3C0OX)
WHEAT GERM (UNII: YR3G369F5A)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
LAURETH-7 (UNII: Z95S6G8201)
PANTHENOL (UNII: WV9CM0O67Z)
DMDM HYDANTOIN (UNII: BYR0546TOW)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
UBIDECARENONE (UNII: EJ27X76M46)
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)
ALCOHOL (UNII: 3K9958V90M)
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)
CHLORELLA VULGARIS (UNII: RYQ4R60M02)
ALLANTOIN (UNII: 344S277G0Z)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
ASCORBYL METHYLSILANOL PECTINATE (UNII: M3PF9237YC)
EDETATE TRISODIUM (UNII: 420IP921MB)
PEG-4 LAURATE (UNII: AYF4VM3N1Z)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
SOYBEAN (UNII: L7HT8F1ZOD)
CERAMIDE 3 (UNII: 4370DF050B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-201-02	1 in 1 CARTON	11/25/2014	
1	NDC:68828-201-01	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 final	part352	11/25/2014	

Labeler - Jafra Cosmetics International (041676479)

Registrant - Jafra Cosmetics International (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing S.A. de C.V.		814732061	manufacture(68828-201)

