CALMING DYNAMICS KIT JAFRA- calming testers
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.

Calming Dynamics Testers

Active Ingredients Purpose

Avobenzone 2.5 % Sunscreen

Octinoxate 7.0 % Sunscreen

Octisalate 4.0 % Sunscreen

Oxybenzone 1.0% Sunscreen

Uses

Helps prevent sunnburn

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 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 project 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 SPF value of 15 or higher and other sun protection measures , including:

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

wear long-sleeve shirts, pants, hats and sunglasses

Inactive ingredients: Water/aqua, C12-15 Alkyl Benzoate, Hydroxyethyl Acrylate/ Sodium Acryloyl dimethyltaurate Copolymer, Squalane, Polysorbate 60, Tridecyl Neopentanoate, Aluminum starch Octenylsuccinate, Saccharide Isomerate, Polyacrylamide, C13-14 Isoparrafin, Laureth-7, Butylene Glycol, Avena Sativa (Oat) Kernel Extract, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, Hemidesmus Indicus Extract, Phyllanthus Emblica Extract, Glycrrhiza Glabra (licorice) Extract, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Panthenol, Tocopheryl Acetate, Dimethicone, Pueraria Lobata Root Extract, Trisodium EDTA, Pentylene Glycol, Propamidobenzoic acid.

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GENTLE CLEANSING LOTION

GENTLE SOOTHING TONER

JAFRA®

CALMING
DYNAMICS

TESTER

Contains: 4 Samples

1 GENTLE HYDRATING DAY CREAM BROAD SPECTRUM SPF 15	7,5 ml ℮ .25 FL OZ (US)
1 GENTLE CLEANSING LOTION	15 ml ℮ .5 FL OZ (US)
1 GENTLE SOOTHING TONER	25 ml ℮ .8 FL OZ (US)
1 GENTLE HYDRATING NIGHT CREAM	7,5 ml ℮ .25 FL OZ (US)

TOTAL 55 ml ℮ 1.8 FL OZ (US)

GENTLE HYDRATING NIGHT CREAM

GENTLE HYDRATING DAY CREAM BROAD SPECTRUM SPF 15

Drug Facts

Active ingredients	Purpose
Avobenzone 2.5%	Sunscreen
Octisalate 7%	Sunscreen
Octocrylene 4%	Sunscreen
Oxybenzone 1%	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

Warnings

For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

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

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
- 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. - 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses

Drug Facts (continued)

Inactive ingredients

Water/Aqua,Hydroxyethyl Acrylate/ Sodium Acryloyldimethyltaurate Copolymer, Squalane, Polysorbate 60, Tridecyl Neopentanoate, Aluminum Starch Octenylsuccinate, Saccharide Isomerate, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Butylene Glycol, Avena Sativa (Oat) Kernel Extract, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, Hemidesmus Indicus Extract, Phyllanthus Emblica Extract, Glycyrrhiza Glabra (Licorice) Extract, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Panthenol, Tocopheryl Acetate, Dimethicone, Pueraria Lobata Root Extract, Trisodium EDTA, Pentylene Glycol, Hydroxyphenyl Propamidobenzoic Acid

Other information

- protect this product from excessive heat and direct sun

Tester - not for resale / Muestra solamente. No etiquetado para su venta individual.
Tester - nicht zum Wiederverkauf bestimmt / Tester - vietata la vendita

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 2273 (antes 515), C.P. 01710,
Distrito Federal, México. JAFRA es Marca Registrada

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

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Jafra

Calming Dynamics

Tester

Contains:4 samples

1 Gentle Hydrating Night Cream/ 1 Gentle Cleansing Lotion/ 1 Gentle Soothing Toner/ 1 Gentle Hydrating Day Cream Broad Spectrum SPF 15

Cont. Net. 60 ml 2 Fl Oz (US)

CALMING DYNAMICS KIT JAFRA

calming testers kit

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:68828-152

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-152-01	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	7.4 mL
Part 2	1 TUBE	7.4 mL
Part 3	1 BOTTLE	7.4 mL
Part 4	1 BOTTLE	7.4 mL

Part 1 of 4

GENTLE HYDRATING DAY BROAD SPECTRUM SPF 15 JAFRA

avobenzone, octinoxate, octisalate, oxybenzone cream

Product Information

Item Code (Source)	NDC:68828-153		
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (AVOBENZONE)	AVOBENZONE	2.5 g in 100 mL
OCTINOXATE (OCTINOXATE)	OCTINOXATE	7.0 g in 100 mL
OCTISALATE (OCTISALATE)	OCTISALATE	4.0 g in 100 mL
OXYBENZONE (OXYBENZONE)	OXYBENZONE	1.0 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)	
SQUALANE	
POLYSORBATE 60	
TRIDECYL NEOPENTANOATE	
ALUMINUM STARCH OCTENYLSUCCINATE	
SACCHARIDE ISOMERATE	
POLYACRYLAMIDE (1500 MW)	
C13-14 ISOPARAFFIN	
LAURETH-7	
BUTYLENE GLYCOL	
OAT	
PHENOXYETHANOL	
HEXYLENE GLYCOL	
CAPRYLYL GLYCOL	
POTASSIUM SORBATE	
LICORICE	
CHONDRUS CRISPUS	
PANTHENOL	
.ALPHA.-TOCOPHEROL ACETATE	
DIMETHICONE	
PUERARIA MONTANA VAR. LOBATA ROOT	
EDETATE TRISODIUM	
PENTYLENE GLYCOL	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.4 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/14/2012	

Part 2 of 4

GENTLE HYDRATING NIGHT JAFRA

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER**	
INGR	**MEDIUM-CHAIN TRIGLYCERIDES**	
INGR	**ALKYL (C12-15) BENZOATE**	
INGR	**GLYCERYL MONOSTEARATE**	
INGR	**POLYACRYLAMIDE (1500 MW)**	
INGR	**C13-14 ISOPARAFFIN**	
INGR	**LAURETH-7**	
INGR	**LICORICE**	
INGR	**BUTYLENE GLYCOL**	
INGR	**OAT**	
INGR	**CETYL ALCOHOL**	
INGR	**PANTHENOL**	
INGR	**DIMETHICONE**	
INGR	**TOCOPHEROL**	
INGR	**GINGER**	
INGR	**LEVOMENOL**	
INGR	**XYLITOL**	
INGR	**DMDM HYDANTOIN**	
INGR	**PEG-4 LAURATE**	
INGR	**IODOPROPYNYL BUTYLCARBAMATE**	
INGR	**EDETATE TRISODIUM**	
INGR	**TANGERINE PEEL**	
INGR	**PUMMELO**	
INGR	**PELARGONIUM GRAVEOLENS FLOWERING TOP**	
INGR	**ORANGE PEEL**	
INGR	**DIPROPYLENE GLYCOL**	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.4 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/14/2012	

Part 3 of 4

GENTLE CLEANSING JAFRA

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER**	
INGR	**ETHYLHEXYL STEARATE**	
INGR	**ISOPROPYL PALMITATE**	
INGR	**GLYCERIN**	
INGR	**POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE**	
INGR	**HYDROGENATED COCO-GLYCERIDES**	
INGR	**SODIUM POLYACRYLATE (8000 MW)**	
INGR	**DMDM HYDANTOIN**	
INGR	**IODOPROPYNYL BUTYLCARBAMATE**	
INGR	**ALLANTOIN**	
INGR	**PANTHENOL**	
INGR	**TOCOPHEROL**	
INGR	**BUTYLENE GLYCOL**	
INGR	**OAT**	
INGR	**LICORICE**	
INGR	**EDETATE DISODIUM**	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.4 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/14/2012	

Part 4 of 4

GENTLE SOOTHING TONER JAFRA

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER**	
INGR	**PROPYLENE GLYCOL**	
INGR	**SODIUM PYRROLIDONE CARBOXYLATE**	
INGR	**GLYCERIN**	
INGR	**LICORICE**	

INGR	**BUTYLENE GLYCOL**	
INGR	**PANTHENOL**	
INGR	**ALLANTOIN**	
INGR	**HAMAMELIS VIRGINIANA TOP**	
INGR	**OAT**	
INGR	**POLYSORBATE 20**	
INGR	**DIAZOLIDINYL UREA**	
INGR	**IODOPROPYNYL BUTYLCARBAMATE**	
INGR	**EDETATE TRISODIUM**	
INGR	**PUMMELO**	
INGR	**PELARGONIUM GRAVEOLENS FLOWERING TOP**	
INGR	**ORANGE PEEL**	
INGR	**DIPROPYLENE GLYCOL**	
INGR	**CITRIC ACID MONOHYDRATE**	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.4 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/14/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/14/2012	

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(68828-152, 68828-153)