

TENDER MOMENTS SPF 45- homosalate octinoxate octisalate oxybenzone titanium dioxide octocrylene lotion

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.

TENDER MOMENTS SPF 45

SUNSCREEN ACTIVE INGREDIENT (SPF 45): TITANIUM DIOXIDE,
OXYBENZONE/BENZOPHENONE-3, HOMOSALATE, OCTINOXATE, OCTISALATE,
OCTOCRYLENE

PURPOSE: SUNSCREEN

OTHER INGREDIENTS: WATER/AQUA, ALUMINA, DIMETHICONE, SODIUM
DIHYDROXYCETYL PHOSPHATE, GLYCERYL STEARATE SE, ADIPIC ACID/DIETHYLENE
GLYCOL/GLYCERIN CROSSPOLYMER, PVPE/ICOSENE COPOLYMER, AVENA SATIVA (OAT)
KERNEL EXTRACT, PANTHENOL, TOCOPHERYL ACETATE, BUTYLENE GLYCOL, CETYL
ALCOHOL, XANTHAN GUM, FRAGRANCE/PARFUM, DMDM HYDANTOIN, PEG-4
LAURATE, IODOPROPYNYL BUTYLCARBAMATE, TRISODIUM EDTA,
[FRAGRANCE/PARFUM CONTAINS: CITRONELLOL, GERANIOL, HEXYL CINNAMAL,
HYDROXYCITRONELLOL, BUTYLPHENYL METHYLPROPIONAL (LILLIAL), LINALOL,
ALPHA-ISOMMETHYL IONONE]

BABY BLOCK SPF 45

APPLY WATER-RESISTANT SUNSCREEN 20 MINUTES BEFORE SUN EXPOSURE.

DISCONTINUE USE IF SIGNS OF IRRITATION APPEAR.

KEEP OUT OF REACH OF CHILDREN.

TENDER MOMENTS
BABY BLOCK SPF 45

JAFRA



Tender Moments

**BABY BLOCK SPF 45
CREMA BLOQUEADORA
PARA BEBÉ FPS 45**

JAFRA

50 ml e 1.7 FL OZ (US)

INTENSIVER BABY SONNENSCHUTZ SPF 45

PROTEZIONE SOLARE BAMBINI SPF 45

Apply water-resistant, sunscreen 20 minutes before sun exposure.

Warnings: For external use only. Avoid contact with eyes. Discontinue use if signs of irritation appear. Seek the advice of a physician prior to use on children under 6 months of age. Keep out of reach of children.

Instrucciones de uso: Aplicar 20 minutos antes de exponerse al sol. Repita la aplicación después de la exposición prolongada al agua o transpiración excesiva. El Factor de Protección Solar 45 (FPS 45) permite exponerse al sol cuarenta y cinco veces más que el tiempo sin protección solar. Este producto es libre de aceite y resistente al agua.

Precaución: Sólo para uso externo. Evite el contacto con los ojos. Descontinúe su uso en caso de irritación o salpullido. Para uso en niños menores de 6 meses consulte a su médico. No se deje al alcance de los niños.

FPS = Factor de Protección Solar.

SUNSCREEN ACTIVE INGREDIENTS (SPF 45): Titanium Dioxide, Oxybenzone/Benzophenone-3, Homosalate, Octinoxate, Octisalate, Octocrylene **OTHER INGREDIENTS:** Water/Aqua, Alumina, Dimethicone, Sodium Dihydroxycetyl Phosphate, Glyceryl Stearate SE, Adipic Acid/Diethylene Glycol/Glycerin Crosspolymer, PVP/Eicosene Copolymer, Avena Sativa (Oat) Kernel Extract, Panthenol, Tocopheryl Acetate, Butylene Glycol, Cetyl Alcohol, Xanthan Gum, Fragrance/Parfum, DMDM Hydantoin, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium EDTA, [Fragrance/Parfum contains: Citronellol, Geraniol, Hexyl Cinnamal, Hydroxycitronellal, Butylphenyl Methylpropional (Lillial), Linalool, Alpha-Isomethyl Ionone]

INGREDIENTES: Agua, Homosalato, Metoxicinamato de Octilo, Dióxido de Titanio, Alúmina, Dimeticona, Benzofenona-3, Salicilato de Octilo, Dihidroxicetilfosfato de Sodio, SE Estearato de Glicerilo, Cospolímero de Glicerina/Acido Adípico/Dietilenglicol, Copolímero PVP/Eicoseno, Octocrileno, Extracto de Avena (Avena Sativa), Pantenol, Acetato de Tocoferilo, Butilenglicol, Alcohol Cetílico, Goma Xantán, Fragancia, Hidantoína DMDM, PEG-4 Laurato, Yodopropinil Butilcarbamato, EDTA Trisódico, [Fragancia contiene: Citronelol, Geraniol, a-hexilcinamaldehído, Hidroxicitronelal, 2-(4-terc-butilbencil)propionaldehído, Linalol, 3-metil-4-(2,6,6-trimetil-2-ciclohexen-1-il)buten-2-ona]

Contains: Oxybenzone / Enthält: Oxybenzon / Contiene: Oxybenzona

Made in Mexico for:

Jafra Cosmetics International, Inc.

Westlake Village, CA 91361

www.JAFRA.com

Hecho en México para:

Distribuidora Comercial Jafra, S.A. de C.V.

Bvd. Adolfo López Mateos 515,

Col. Tlacopac, México, D. F., 01040



Jafra y Tender Moments son Marcas Registradas en México;

Reg US Pat & TM off

LOS ANGELES - ZURICH - MUNICH

MEXICO CITY - MILAN

WARNINGS: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES.

SEEK THE ADVICE OF A PHYSICIAN PRIOR TO USE ON CHILDREN UNDER 6 MONTHS OF

AGE.

TENDER MOMENTS SPF 45

homosalate octinoxate octisalate oxybenzone titanium dioxide octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.7 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JH2SW)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIETHYLENE GLYCOL ADIPATE (UNII: 6KE5V549E0)	
OAT (UNII: Z6J799EAJK)	
POVIDONE K30 (UNII: U725QWY32X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-4 LAURATE (UNII: AYP4VM3N1Z)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-060-13	50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/24/2012	

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

Revised: 5/2012

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