

**TENDER MOMENTS BABY SUNSCREEN BROAD SPECTRUM SPF 50 JAFRA- avobenzene, homosalate, octisalate, octocrylene, oxybenzone liquid
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 Baby Sunscreen

Active ingredients	Purpose
Avobenzene 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 5%	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 by the sun.

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

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs.

Warnings

For external use only

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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Avena Sativa (Oat) Kernel Extract, Behenyl Alcohol, Butylene Glycol, Chlorphenesin, Cyclopentasiloxane, Disodium



EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glyceryl Stearate, Lauroyl Lysine, Methylisothiazolinone, Panthenol, PEG-100 Stearate, Sodium Hydroxide, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water/Aqua.

Jafra

Tender Moments

Baby Sunscreen Broad Spectrum SPF 50

50 ml 1.7 Fl Oz

<p>Drug Facts</p> <p>Active ingredients Purpose</p> <p>Avobenzene 3%.....Sunscreen Homosalate 10%.....Sunscreen Octisalate 5%.....Sunscreen Octocrylene 7%.....Sunscreen Oxybenzone 5%.....Sunscreen</p> <p>Uses</p> <ul style="list-style-type: none"> 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 <p>Warnings For external use only</p> <p>Do not use on damaged or broken skin</p> <p>Stop use and ask a doctor if rash occurs</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> 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 <p>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:</p> <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. - 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses <p>Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Avena Sativa (Oat) Kernel Extract, Behenyl Alcohol, Butylene Glycol, Chlorphenesin, Cyclopentasiloxane, Disodium EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glyceryl Stearate, Lauroyl Lysine, Methylisothiazolinone, Panthenol, PEG-100 Stearate, Sodium Hydroxide, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water/Aqua</p> <p>Other information</p> <ul style="list-style-type: none"> protect this product from excessive heat and direct sun 	 <p>JAFRA Tender Moments</p>  <p>BABY SUNSCREEN BROAD SPECTRUM SPF 50</p> <p>50 ml e 1.7 FL OZ (US)</p>
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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.
Bld. Adolfo López Mateos 2273 (antes 515),
C.P. 01710, Distrito Federal, México.
JAFRA y Tender Moments son
Marcas Registradas en México; Reg US Pat & TM off
LOS ANGELES - ZURICH - MUNICH
MEXICO CITY - MIAMI - MOSCOW

TENDER MOMENTS BABY SUNSCREEN BROAD SPECTRUM SPF 50 JAFRA

avobenzene, homosalate, octisalate, octocrylene, oxybenzone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-177
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
OAT (UNII: Z6J799EAJK)	
DOCOSANOL (UNII: 9G1OE216XY)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAUROYL LYSINE (UNII: 113171Q70B)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PANTHENOL (UNII: WV9CM0O67Z)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-177-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	09/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/30/2013	

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(68828-177)