

**4-IN-1 BROAD SPECTRUM SPF 50 SUNSCREEN- avobenzone, homosalate, octocrylene, octisalate, oxybenzone cream**

**Bio Jouvance**

*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.*

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**4-IN-1 Broad Spectrum SPF 50 Sunscreen**

**Purpose Sunscreen**

Avobenzone 3.0%, Homosalate 15%, Octocrylene 8.0%, Octisalate 5.0%, Oxybenzone 5.0%

**Uses**

helps prevent sunburn

if used as directed with other sun protection measures (see directions), decrease 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 Poison Control Center right away.

Stop use and ask a Physician if rash occurs.

For external use only. Do not used on damaged or broken skin. When using this product, keep out of eyes. Rinse with water to remove.

- apply liberally 15 minutes before sun exposure
- re-apply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every two hours
- **Sun Protection Measures.** Spending time under the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with an SPF of 15 or higher, and other sun protection measures, including:
  - limit time under the sun, especially from 10:00 a.m. to 2:00 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
  - Children under 6 months: Ask a Physician if exposure would be advised.

water, stearic acid, glyceryl stearate, PEG-100 stearate, elaeis guineensis kernel oil, aloe barbadensis leaf extract, retinyl palmitate, pyridoxine hydrochloride cyanocobalamin, ascorbic acid, tocopheryl acetate, sodium hyaluronate crosspolymer, dimethicone, polysorbate 60, carbomer, triethanolamine, DMDM hydantoin, diazolidinyl urea, iodopropynyl butylcarbamate

protect this product from excessive heat and direct sun

**Questions or comments?**

Call toll free 1-800-272-1716

BIO JOUVANCE

PARIS

4-in-1 BROAD SPECTRUM SPF 50 SUNSCREEN

FACE/BODY

2 FL. OZ. 60 ml

DISTRIBUTED BY BIOJOUVANCE INC.

LOS ANGELES, CA 90039

WWW.BIOJOUVANCE.COM

BIOJOUVANCE

PARIS

4-IN-1  
BROAD SPECTRUM  
SPF 50 SUNSCREEN

FACE / BODY

2 fl. oz. 60 ml

<b>Drug Facts</b>
<b>Active Ingredients Purpose Sunscreen</b> Avobenzene 3.0%, Homosalate 15%, Octocrylene 8.0%, Octisalate 5.0%, Oxybenzone 5.0%
<b>Uses</b> • 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.
<b>Warnings</b> • 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. • Stop use and ask a Physician if rash occurs. • Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.
<b>Directions</b> • apply liberally 15 minutes before sun exposure • re-apply: • after 40 minutes of swimming or sweating • immediately after towel drying • at least every two hours • <b>Sun Protection Measures.</b> Spending time under the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with an SPF of 15 or higher, and other sun protection measures, including: • limit time under the sun, especially from 10:00 a.m. to 2:00 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses Children under 6 months: Ask a Physician if exposure would be advised.
<b>Inactive Ingredients:</b> water, stearic acid, glyceryl stearate, PEG-100 stearate, elaeis guineensis (palm) kernel oil, aloe barbadensis leaf extract, retinyl palmitate, pyridoxine hydrochloride, cyanocobalamin, ascorbic acid, tocopheryl acetate, sodium hyaluronate crosspolymer, dimethicone, polysorbate 60, carbomer, triethanolamine, DMDM hydantoin, diazolidinyl urea, iodopropynyl butylcarbamate
<b>Other information</b> • protect this product from excessive heat and direct sun
<b>Questions or comments?</b> Call toll free 1-800-272-1716

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avobenzene, homosalate, octocrylene, octisalate, oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80030-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
PEG-100 STEARATE (UNII: YD01N1999R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>PALM KERNEL OIL</b> (UNII: B0S90M0233)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80030-001-01	60 mL in 1 TUBE; Type 0: Not a Combination Product	08/19/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/19/2020	

**Labeler** - Bio Jouvance (013516194)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Science Laboratories, LLC		018454384	manufacture(80030-001)

Revised: 8/2020

Bio Jouvance