

**JACKET SPF-50 BROAD SPECTRUM SUNSCREEN- zinc oxide, homosalate, octisalate, octocrylene lotion**  
**BALSHI MD DERMACEUTICALS**

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**JACKET SPF-50 Broad Spectrum Sunscreen**

***Drug Facts***

***Active Ingredients***

Zinc Oxide 6.00%

Homosalate 10.00%

Octisalate 5.00%

Octocrylene 5.00%

***Purpose***

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.

***When using this product***

keep out of eyes. Rinse with water to remove.

***Stop use and consult physician***

if irritation or rash develops

***Keep out of reach of children.***

If product is swallowed, get medical attention or contact poison control center immediately.

***Directions***

• Apply liberally 15 minutes before sun exposure • Reapply: \*At least every 2 hours  
\*Immediately after swimming, sweating or towel drying Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including: \*Limit time in the sun, especially between 10am -2pm \*Wear long sleeve shirts, pants, hats and sunglasses \*For children under 6 months, consult a physician.

### **Sun Protection Measures:**

### ***Other Ingredients***

Acrylates Copolymer, Allantoin, Aloe Barbadensis (Aloe Vera Gel) Juice, Aqua (Deionized Water), a-Arbutin, Ascorbic Acid (Vitamin C), Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Cetareth 20, Cetearyl Olivat, Cetyl Alcohol, Cucumis Sativus (Cucumber) Fruit Extract, Cyclopentasiloxane, Cyclotetrasiloxane, Cymbopogon Schoenanthus (Lemongrass) Oil, Dimethicone, Ethylhexylglycerin, Ethylhexyl Palmitate, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Oil, Magnesium Aluminum Silicate, Phenoxyethanol, Polysorbate 20, Punica Granatum (Pomegranate) Extract, Sorbitan Olivat, Stearyl Alcohol, Tocopheryl Acetate (Vitamin E), Tridecyl Salicylate, Zema (Corn) Propanediol

### ***Other Information***

Protect this product from excessive heat and direct sunlight.

### **Package Labeling:**

# JACKET®

**SPF 50+**

UVA / UVB BROAD SPECTRUM SPF 50+ SUNSCREEN

WATER RESISTANT (80 MINUTES)

4 FL OZ (120ML)

Jacket® is an antioxidant-rich **SPF 50+** sunscreen that repairs and protects your skin while you wear it.

### Drug Facts

Active Ingredients	Purpose
Zinc Oxide 6.00%	Sunscreen
Homosalate 10.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 5.00%	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 • When using this product keep out of eyes. Rinse with water to remove • Stop use and consult physician if irritation or rash develops • Keep out of reach of children. If product is swallowed, get medical attention or contact poison control center immediately.

### Directions

• Apply liberally 15 minutes before sun exposure • Reapply: \*At least every 2 hours \*Immediately after swimming, sweating or towel drying • **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including: \*Limit time in the sun, especially between 10am - 2pm \*Wear long sleeve shirts, pants, hats and sunglasses \*For children under 6 months, consult a physician.

**Other Ingredients** Acrylates Copolymer, Allantoin, Aloe Barbadensis (Aloe Vera Gel) Juice, Aqua (Deionized Water), a-Arbutin, Ascorbic Acid (Vitamin C), Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Ceteareth 20, Cetearyl Oliviate, Cetyl Alcohol, Cucumis Sativus (Cucumber) Fruit Extract, Cyclopentasiloxane, Cyclotetrasiloxane, Cymbopogon Schoenanthus (Lemongrass) Oil, Dimethicone, Ethylhexylglycerin, Ethylhexyl Palmitate, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Oil, Magnesium Aluminum Silicate, Phenoxyethanol, Polysorbate 20, Punica Granatum (Pomegranate) Extract, Sorbitan Oliviate, Stearyl Alcohol, Tocopheryl Acetate (Vitamin E), Tridecyl Salicylate, Zemea (Corn) Propanediol.

### Other Information

Protect this product from excessive heat and direct sunlight.

Manufactured for:  
Balshi Dermatology  
Delray Beach, FL 33445  
561.272.6000  
[jacketsunscreen.com](http://jacketsunscreen.com)

## JACKET SPF-50 BROAD SPECTRUM SUNSCREEN

zinc oxide, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71070-868
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)</b> (UNII: JZ1374NL9E)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>CETYL ALCOHOL</b> (UNII: 936JT6JCN)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)	
<b>CYBOPOGON CITRATUS LEAF</b> (UNII: 06JMS448M5)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>LICORICE</b> (UNII: 61ZBX54883)	
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POMEGRANATE</b> (UNII: 56687D1Z4D)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>CORN</b> (UNII: 0N8672707O)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71070-868-04	120 mL in 1 TUBE; Type 0: Not a Combination Product	04/15/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/15/2019	

**Labeler** - BALSHI MD DERMACEUTICALS (010011434)

Revised: 11/2023

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