

**JACKET SPF 50- zinc oxide, octinoxate, octisalate, octisalate cream**  
**Balshi MD Dermaceuticals**

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**JACKET SPF 50+ CREAM**

***Drug Facts***

***Active Ingredients***

Zinc Oxide 7.50%

Octinoxate 7.50%

Octisalate 5.00%

Oxybenzone 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 if 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 •

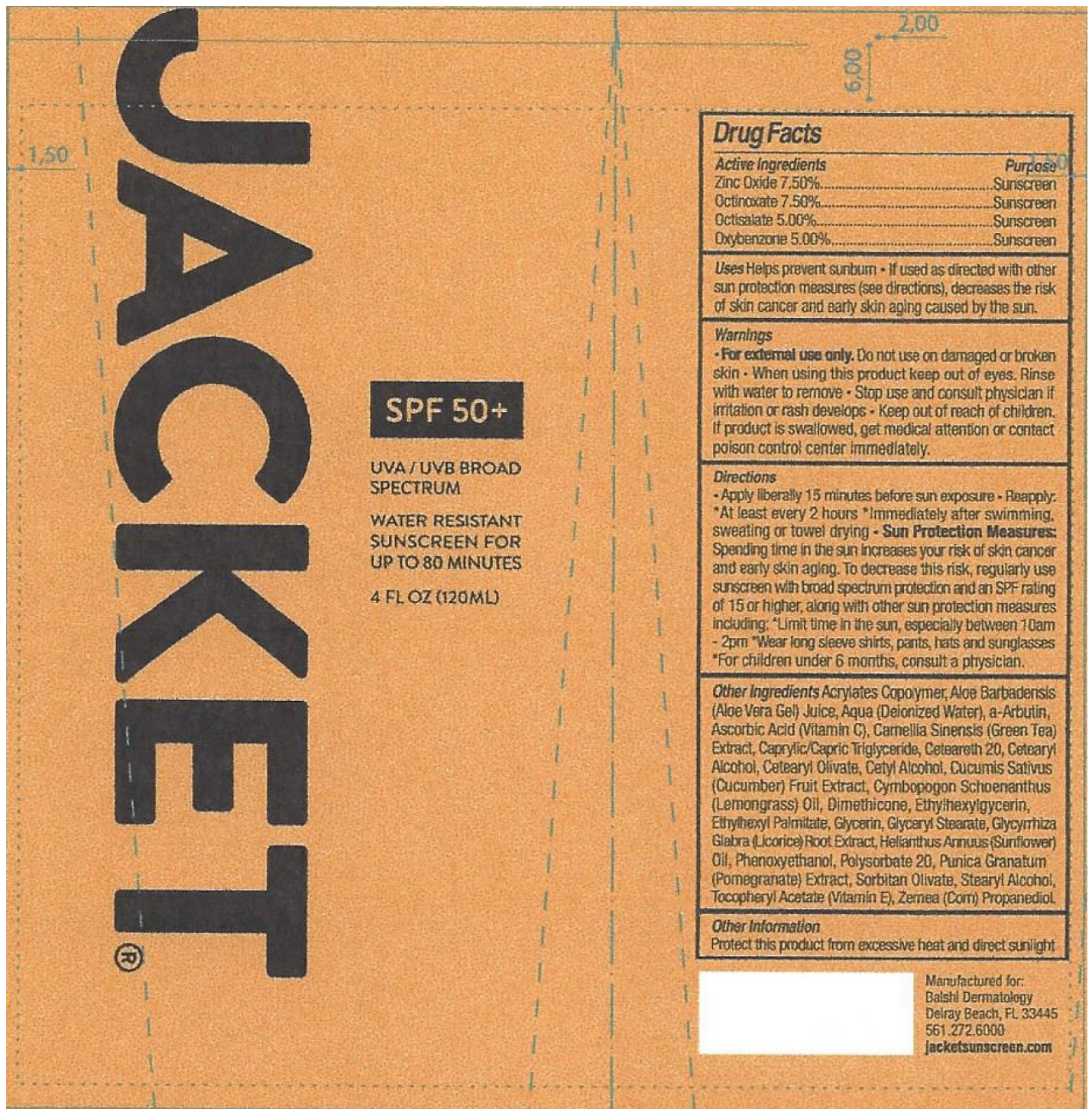
Immediately after swimming, sweating or towel drying

- 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: **Sun Protection Measures:**
- 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, 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 Alcohol, Cetearyl Oliviate, Cetyl Alcohol Cucumis  
Sativus (Cucumber) Fruit Extract, Cymbopogon Schoenanthus (Lemongrass) Oil,  
Dimethicone, Ethylhexylglycerin, Ethylhexyl Palmitate, Glycerin, Glyceryl Stearate,  
Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Oil,  
Phenoxyethanol, Polysorbate 20, Punica Granatum (Pomegranate) Extract, Sorbitan  
Oliviate, Stearyl Alcohol, Tocopheryl Acetate (Vitamin E), Zema (Corn), Propanediol

### **Package Labeling:**



## JACKET SPF 50

zinc oxide, octinoxate, octisalate, octisalate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71070-768
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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#### Drug Facts

Active Ingredients	Purpose
Zinc Oxide 7.50%	Sunscreen
Octinoxate 7.50%	Sunscreen
Octisalate 5.00%	Sunscreen
Oxybenzone 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, Aloe Barbadensis (Aloe Vera Gel) Juice, Aqua (Deionized Water), a-Arbutin, Ascorbic Acid (Vitamin C), Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Cetearith 20, Cetearyl Alcohol, Cetearyl Oliviate, Cetyl Alcohol, Cucumis Sativus (Cucumber) Fruit Extract, Cymbopogon Schoenanthus (Lemongrass) Oil, Dimethicone, Ethylhexylglycerin, Ethylhexyl Palmitate, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Oil, Phenoxyethanol, Polysorbate 20, Punica Granatum (Pomegranate) Extract, Sorbitan Oliviate, Stearyl Alcohol, Tocopheryl Acetate (Vitamin E), 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  
[jacketsunscreens.com](http://jacketsunscreens.com)

<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	75 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ARBUTIN</b> (UNII: C5INA23HXF)	
<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>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>CUCUMBER</b> (UNII: YY7C30VXJT)	
<b>CYBOPOGON SCHOENANTHUS OIL</b> (UNII: XE7K568ILO)	
<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>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)	
<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</b> (UNII: H4N855PNZ1)	
<b>CORN</b> (UNII: 0N8672707O)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71070-768-04	1 in 1 CARTON	11/18/2016	
1		113 g in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/18/2016	

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**Labeler** - Balshi MD Dermaceuticals (010011434)

Revised: 11/2023

Balshi MD Dermaceuticals