

BLUE LIZARD ACTIVE SPF 50 SUNSCREEN- octisalate and titanium dioxide and zinc oxide lotion
Crown Laboratories

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.

Blue Lizard Active SPF 50 Sunscreen

Active Ingredients

Octisalate - 5%

Titanium Dioxide - 5.36%

Zinc Oxide - 10%

Purpose

Sunscreen

Uses

- Helps prevent sunburn and photodamage caused by UVA/UVB exposure
- Higher SPF gives more sunburn protection
- If used as directed with other sun protection measures (see Directions), decreases the risks of skin cancer and early skin aging caused by the sun

Warnings

- When using this product • Keep out of eyes. Rinse with water to remove
- Stop use and ask doctor if • Rash or irritation occurs
- Do not use • On damaged or broken skin • If allergic to any ingredient
- If swallowed, get medical help or contact a Poison Control Center

Directions

- **Shake well prior to use**
- Apply liberally to dry skin 15 minutes before sun exposure
- For topical use only
- Keep out of reach of children • 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-sleeved shirts, pants, hats, and sunglasses.
- **Reapply to dry skin:** • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours

Other Information

- Protect the product in this container from excessive heat and direct sun
- May stain some fabrics

Inactive Ingredients

Alumina, Aluminum Stearate, Beeswax, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Diisopropyl Sebacate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Hexyl Laurate, Hydrogenated Castor Oil, Isostearyl Isostearate, L-Arginine, Methyl Glucose Dioleate, Methylpropanediol, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxyethanol, Phenylpropanol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polyurethane-35, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Trimethylsiloxysilicate, VP Hexadecene Copolymer

Questions ?

Visit www.bluelizardsunscreen.com or call **800.877.8869**

Crown Laboratories, Inc., Johnson City, TN 37604

Blue Lizard Active 5oz Tube

BLUE LIZARD

AUSTRALIAN SUNSCREEN

50+

UVA/UVB PROTECTION

BROAD SPECTRUM

SPF 50+

ACTIVE

mineral-based sunscreen

combining mineral and chemical UV protectors

Smart Cap TECHNOLOGY

CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT (80 MINUTES)



BLUE LIZARD[®]

AUSTRALIAN SUNSCREEN

50⁺

UVA / UVB PROTECTION
BROAD SPECTRUM
SPF 50⁺

TRUSTED BY
DERMATOLOGISTS
FOR OVER 20 YEARS



ACTIVE

mineral-based sunscreen
combining mineral and chemical UV protectors

Smart Cap[™] TECHNOLOGY
CAP CHANGES COLOR IN HARMFUL UV LIGHT

WATER RESISTANT
(80 MINUTES)



Mineral-Based Sunscreen

Combining mineral and chemical UV protectors for water-resistant performance you can trust.

<i>Drug Facts</i>	Made in USA
<p>Active Ingredients</p> <p>Octisalate 5% Titanium Dioxide 5.36% Zinc Oxide 10%</p>	<p>Purpose</p> <p>Sunscreen Sunscreen Sunscreen</p>
<p>Uses • Helps prevent sunburn and photodamage caused by UVA/UVB exposure • Higher SPF gives more sunburn protection • If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</p>	
<p>Warnings</p> <ul style="list-style-type: none"> • When using this product • Keep out of eyes. Rinse with water to remove • Stop use and ask a doctor if • Rash or irritation occurs • Do not use • On damaged or broken skin • If allergic to any ingredient • If swallowed, get medical help or contact a Poison Control Center 	
<p>Directions • Shake well prior to use • Apply liberally to dry skin 15 minutes before sun exposure • For topical use only</p> <ul style="list-style-type: none"> • Keep out of reach of children • 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-sleeved shirts, pants, hats, and sunglasses. • Reapply to dry skin: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours 	
<p>Other Information • Protect the product in this container from excessive heat and direct sun • May stain some fabrics</p>	
<p>Inactive Ingredients: Alumina, Aluminum Stearate, Beeswax, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Diisopropyl Sebacate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Hexyl Laurate, Hydrogenated Castor Oil, Isostearyl Isostearate, L-Arginine, Methyl Glucose Dioleate, Methylpropanediol, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxyethanol, Phenylpropanol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polyurethane-35, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylsilane, Trimethylsiloxysilicate, VP/Hexadecene Copolymer</p>	
<p>Questions? Visit www.bluelizardsunscreen.com or call 800.877.8869</p>	



5 fl oz (148 ml)



P11863.00

Crown Laboratories, Inc.
Johnson City, TN 37604

BLUE LIZARD ACTIVE SPF 50 SUNSCREEN

octisalate and titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0316-2072
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	55.5 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	59.5 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	111 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ARGININE (UNII: 94ZLA3W45F)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-7 HYDROGENATED CASTOR OIL (UNII: WE09129TH5)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
POLYURETHANE-35 (NOT MORE THAN 500 MPa.S AT 40%) (UNII: Q2LKX89BE0)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2072-30	89 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2021	
2	NDC:0316-2072-50	259 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2021	
3	NDC:0316-2072-45	148 mL in 1 TUBE; Type 0: Not a Combination Product	02/09/2021	
4	NDC:0316-2072-40	1 in 1 CARTON	02/24/2021	
4		148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/09/2021	

Labeler - Crown Laboratories (079035945)

Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2072)

Revised: 10/2021

Crown Laboratories