

BLUE LIZARD FACE- sunscreen gel

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 Face

Active Ingredients

Octinoxate 5.5%

Zinc Oxide 8.0%

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 risk 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 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

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:**
 - At least every 2 hours

- Use a water resistant sunscreen if swimming or sweating

Other Information

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

Inactive Ingredients

Beeswax, BHT, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Caffeine, Camellia sinesis Leaf (Green Tea) Extract, Caprylyl Glycol, Chlorphenesin, Cyclomethicone, Dimethoxydiphenylsilane, Isotearyl Alcohol, Laureth-7, Lauryl PEG/PPG 18/18 Methicone, Phenoxyethanol, Polyacrylamide, Purified Water, Sodium Hyaluronate, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane

Questions?

Visit **www.bluelizard.net** or call **800.877.8869**

Crown Laboratories, Inc., Johnson City, TN 37604

Blue Lizard Face Label

BLUE LIZARD

AUSTRALIAN SUNSCREEN

30+

UVA/UVB PROTECTION

BROAD SPECTRUM

SPF 30+

TRUSTED BY DERMATOLOGISTS FOR OVER 20 YEARS

FACE

mineral-based sunscreen

combining mineral and chemical UV protectors

Smart Cap TECHNOLOGY

CAP TURNS BLUE IN HARMFUL UV LIGHT

LIGHTWEIGHT DAILY

SUN PROTECTION

P6138.11

BLUE LIZARD[®]

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30⁺

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BROAD SPECTRUM
SPF 30+

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FACE

mineral-based sunscreen
combining mineral and chemical UV protectors

Smart Cap[™] TECHNOLOGY
CAP TURNS **BLUE** IN HARMFUL UV LIGHT

LIGHTWEIGHT DAILY
SUN PROTECTION

3 oz (85 g)



Mineral-Based Sunscreen

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

Drug Facts

Made in USA

Active Ingredients

Octinoxate 5.5%
Zinc Oxide 8.0%

Purpose

Sunscreen
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 risk 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 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

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:** • At least every 2 hours • Use a water resistant sunscreen if swimming or sweating

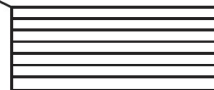
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Inactive Ingredients: Beeswax, BHT, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Caffeine, Camellia Sinensis Leaf (Green Tea) Extract, Caprylyl Glycol, Chlorphenesin, Cyclomethicone, Dimethoxydiphenylsilane, Isostearyl Alcohol, Laureth-7, Lauryl PEG/PPG 18/18 Methicone, Phenoxyethanol, Polyacrylamide, Purified Water, Sodium Hyaluronate, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane

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Crown Laboratories, Inc.
Johnson City, TN 37604



BLUE LIZARD FACE

sunscreen gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0316-2055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	55 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHOXYDIPHENYLSILANE (UNII: 02QB6788GC)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CAFFEINE (UNII: 3G6A5W338E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWW)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2055-10	5 g in 1 POUCH; Type 0: Not a Combination Product	04/06/2010	10/01/2021
2	NDC:0316-2055-30	85 g in 1 TUBE; Type 0: Not a Combination Product	04/06/2010	03/31/2024
3	NDC:0316-2055-40	141.7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2010	08/31/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/06/2010	03/31/2024

Registrant - Crown Laboratories (079035945)

Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2055)

Revised: 12/2021

Crown Laboratories