

**BLUE LIZARD BABY- 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.*

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**Blue Lizard Baby**

**Active Ingredients**

Titanium Dioxide - 5%

Zinc Oxide - 10%

**Drug Facts - 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:**
  - 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, C12-15 Alkyl Benzoate, Caprylyl Glycol, Cetyl Dimethicone, Cetyl Dimethicone Copolyol, Chlorphenesin, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Octododecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxyethanol, Polyglyceryl-4 Isostearate, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Trimethylated Silica/Dimethicone, VP Hexadecene Copolymer

## **Questions ?**

Visit [www.bluelizard.net](http://www.bluelizard.net) or call **800.877.8869**

Crown Laboratories, Inc., Johnson City, TN 37604

Patents: US#6698590 & 6405867; AU#1998083259

## **Blue Lizard Baby 5oz Label**

Blue Lizard

Australian Sunscreen

Baby

Broad Spectrum SPF 30+

UVA/UVB Protection

Bottle Turns Pink in UV Light

Titanium Dioxide and Zinc Oxide Formula

No Parabens

No Fragrances

Dermatologist Recommended

# BLUE LIZARD<sup>®</sup>

AUSTRALIAN SUNSCREEN



BOTTLE TURNS PINK IN UV LIGHT

**NO** PARABENS | TITANIUM DIOXIDE &  
FRAGRANCES | ZINC OXIDE FORMULA

**DERMATOLOGIST RECOMMENDED**

**BABY**

5 FL OZ (148 mL)

P6667.05

## Drug Facts

Made in USA

### Active Ingredients

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Zinc Oxide 10%

### Purpose

Sunscreen  
Sunscreen

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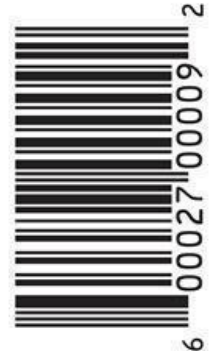
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## BLUE LIZARD BABY

titanium dioxide and zinc oxide lotion

### Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0316-2035
Route of Administration	TOPICAL	DEA Schedule	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (TITANIUM DIOXIDE)	TITANIUM DIOXIDE	54 mg in 1 mL
ZINC OXIDE (ZINC OXIDE)	ZINC OXIDE	108 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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YELLOW WAX
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)
ALKYL (C12-15) BENZOATE
EDETATE DISODIUM
ETHYLHEXYL PALMITATE
ETHYLHEXYL STEARATE
CAPRYLYL GLYCOL
HEXYL LAURATE
HYDROGENATED CASTOR OIL
METHYL GLUCOSE DIOLEATE
CHLORPHENESIN
OCTYLDODECYL NEOPENTANOATE
PEG-7 HYDROGENATED CASTOR OIL
POLYGLYCERYL-4 ISOSTEARATE
PHENOXYETHANOL
PROPANEDIOL
WATER
SORBITAN MONOOLEATE
STEARIC ACID
.ALPHA.-TOCOPHEROL ACETATE
DIMETHICONE
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0)
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-2035-20	37 mL in 1 BOTTLE, PLASTIC		
2	NDC:0316-2035-30	89 mL in 1 TUBE		
3	NDC:0316-2035-40	148 mL in 1 BOTTLE, PLASTIC		
4	NDC:0316-2035-50	259 mL in 1 BOTTLE, PLASTIC		
5	NDC:0316-2035-60	3785 mL in 1 JUG		
6	NDC:0316-2035-10	5 mL in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/08/2003	

**Labeler** - Crown Laboratories (079035945)

**Registrant** - Crown Laboratories (079035945)

### Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-2035)

