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.

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** 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

Drug Facts Made in USA

Active Ingredients	Purpose
Titanium Dioxide 5%	Sunscreen
Zinc Oxide 10%	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
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• Stop use and ask a doctor if • Rash or irritation occurs
• Do not use • On damaged or broken skin • If allergic to any ingredient
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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 Silca/Dimethicone, VP Hexadecene Copolymer

Questions? Visit **www.bluelizard.net** or call **800.877.8869**
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BLUE LIZARD BABY

titanium dioxide and zinc oxide lotion

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	54 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	108 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength

YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
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)	

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)