

BIO ACTIVE COMPLEX SPF 15- zinc oxide cream
ALLURE LABS INC

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.

Drug Facts

Active Ingredients:

Zinc Oxide - 18.9%

Purpose: Sunscreen

Uses: Helps prevent sunburn. If used as directed with other sun protection measures (see Direction), decreases the risk of skin cancer and early skin aging caused by the sun.

For external use only.

Do not use on damaged or broken skin.

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply liberally 15 minutes prior to sun exposure.
- Reapply: after 80 minutes of swimming or sweating. Immediately after towel drying. At least every 2 hours.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in sun sun, especially from 10 am - 2 pm.
 - wear long-sleeve shirts, pants, hats and sunglasses.
 - Children under 6 months: Ask a doctor.

Water, Caprylic/Capric Triglyceride, Polyglyceryl-2 Sesquiosostearate, Cetyl Octanoate, Cera Alba Beeswax, Sodium Hyaluronate, Caprylyl Glycol, Hexylene Glycol, Yeast Extract, Biosaccharide Gum-1, Camellia Sinensis Leaf Extract, Butyrospermum Parkii (Shea butter/Vit. A,E,F), Malus Domestica Fruit Cell Culture, Xanthan Gum, Glycerin, Lecithin, Xanthan Gum, Magnesium Sulfate, Tocopheryl Acetate, Allantoin, Magnesium Stearate, Aluminum Stearate, Isostearic Acid, Polyhydroxystearic Acid, Polyglyceryl-3 Ricinoleate, Phenoxyethanol, Ethylhexylglycerin, Copemicia Cerifera Wax, Oenothera Biennis Oil, Resorcinol.

Protect this product from excessive heat and direct sun.

Call toll free 1-800 830-1491 in the USA.

info@atzen.com

Toll free in USA: 800.830.1491

Email: info@atzen.com

www.atzen.com

Developed in France. Made in USA.

ATZEN®

Advanced Home Spa System

1 2 3 4 5

Step 1: cleanser. Step 2: toner. Optional Step 3: serum &/or corrective product. **Step 4: moisturizer. Step 5: sun screen.**

Use scrub & mask 2 or 3 times a week.

Séquence d'utilisation

1 2 3 4 5

1: nettoyer/ démaquiller, 2: tonifier, 3: sérum and/ou produit correctif (optionnel) 4: crème/gel hydratant*, 5: protection solaire

Utiliser la gommage et le masque 2 à 3 fois par semaine.

Drug Facts

Active Ingredients
Zinc Oxide 12.0% **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 ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
• apply liberally 15 minutes before sun exposure
• use a water-resistant sunscreen if swimming or sweating
• reapply at least every 2 hours
• **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 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-sleeve shirts, pants, hats, and sunglasses
• children under 6 months: Ask a doctor

Inactive Ingredients
Water, Caprylic/Capric Triglyceride (hydrating), Polyglyceryl-2 Sesquisebacarate (Eco-cert approved emulsifier), Cetyl Octanoate (natural emollient), Polyhydroxybutyrate Acid & Polyglyceryl-3 Polymethacrylate & Isocaproic Acid & Lecithin (natural emollient), Cera Alba Beeswax (natural emulsifier), Na Hyaluronate (hydrating), Phenoxylethanol & Caprylyl Glycol & Ethylhexylglycerin & Hexylene Glycol (safe & natural preservatives from plants), Yeast Extract (probiotic from plants), Biosaccharide Gum-1 (F-100gel® from mushroom), Camellia Sinensis Leaf Extract (green leaf antioxidant), Butyrospermum Parkii (shea butter/Vit. A, E, F), Malus Domestica Fruit Cell Culture & Xanthan Gum & Glycerin & Lisdithionin (stem cells from Swiss apples), Magnesium Sulfate (mineral), Tocopherol Acetate (Vit. E), Alantoin (soothing), Magnesium Stearate (mineral), Aluminum Stearate (mineral), Copernicia Cerifera (Carnauba) Wax, Oenothera Biennis (evening primrose) Oil, Passiflora (brazilwood extract)

Other information
• protect this product from excessive heat and direct sun

Questions or comments?
Call toll free 1-800-830-1491 in the USA, info@atzen.com



30 ml/1.0 fl.oz. SKU: A19010
Developed in France | Made in USA



BALANCE™
Age Reverse Safely™

Bio-Active Complex
Silky Complexion, Broad Spectrum

Complexe Bio-Actif
Éclat Soyeux, Écrans Minéraux

SPF15

Sensitive / Allergic Skin

Paraben free, pharmaceutical grade antioxidant formulation.

Sans parabens, de qualité pharmaceutique, protège des radicaux libres.

Sin parabenos, fórmula antioxidante de calidad farmacéutica.

不含苯甲醚類, 應用醫葯級抗氧化配方

Light scent of organic green tea
Light weight emulsion transforms tired & sensitized skin into vibrant, firm & youthful complexion. Protects from pollution & ultraviolet.

Léger parfum de thé vert biologique
Émulsion légère métamorphose fatigué & sensibilisée en un teint éclatant. Protège contre la pollution & les ultraviolets.

Ligero perfume de té verde orgánico
Emulsión ligera: Transforma la piel fatigada y sensitiva en un cutis juvenil, radiante y terso. Protege contra la contaminación y rayos ultravioleta.

有機綠茶的清香
輕質乳液可用於改善疲勞敏感的肌膚。干細胞使其真實并恢復年輕活力。可防止外界污染以及紫外線 (與叔原蛋白)。

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BIO ACTIVE COMPLEX SPF 15

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4163
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	120 mg in 1mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
POLYGLYCERYL-2 SESQUISO STEARATE (UNII: LA272Q68GQ)	
CETYL OCTACOSANOATE (UNII: O7F4812VDX)	

POLYSORBATE 60 (UNII: CAL22UVI4M)
PEG-20 SORBITAN STEARATE (UNII: HD40WR33LC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
YEAST MANNAN (UNII: 91R887N59P)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
ISOSTEARIC ACID (UNII: X33R8U0062)
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)
SHEA BUTTER (UNII: K49155WL9Y)
MALUS DOMESTICA FLOWER (UNII: EF626V855K)
XANTHAN GUM (UNII: TTV12P4NEE)
GLYCERIN (UNII: PDC6A3C0OX)
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)
TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: W11J5UCY5C)
ALLANTOIN (UNII: 344S277G0Z)
MAGNESIUM STEARATE (UNII: 70097M6I30)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)
COPERNICIA ALBA WHOLE (UNII: 2HXP20S5QU)
OENOTHERA BIENNIS (UNII: 76UI55V071)
RESORCINOL (UNII: YUL4LO94HK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4163-2	1 in 1 CARTON	12/18/2017	
1	NDC:62742-4163-1	30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/18/2017	

Labeler - ALLURE LABS INC (926831603)