

BB CREAM BROAD SPECTRUM SPF 25 MEDIUM 01- 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 21.0%

Purpose: Sunscreen

Uses:

- Helps prevent sunburn.
- If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warning: For external use only.

Do not use: on damaged or broken skin.

When using this products:

- 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 generously 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating. Immediately after towel drying. at least every 2 hours.
- **Sun protection measures.** Spending time in the sun increase 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.

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients: Water (Aqua), Caprylic/Capric Triglyceride, Coconut Alkanes, Cetearyl Alcohol, Glycerin, Aloe Barbadosensis Leaf Juice, Glyceryl Stearate, PEG-100 Stearate, Coco-Glucoside, Helianthus Annus, Caprylyl/Capryl Glucoside, Sclerotium Gum, Xanthan Gum, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Lecithin, Pyrus Malus (Apple) Fruit Extract, Cetearyl Glucoside, Tetrahexyldecyl Ascorbate, Butyrospermum Parkii (Shea) Butter, Coco-Caprylate/Caprinate, Tocopherol, Sodium Hyaluronate, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide, C13-14 Isoparaffin, Laureth 7, Hydrolyzed Jojoba Esters, Citric Acid, Anthemis Nobilis Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis (Green Tea) Extract, Triethoxycaprylylsilane, Dimethicone, Fragrance, Limonene, Linalool, May contain +/-, Mica (CI 77019), Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499).

FLOETIC BEAUTY LLC, DIST.

CLYDE HILL, WA 98004

MADE IN USA

WWW.FLOETICBEAUTY.COM

<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> <tr> <td>Zinc Oxide 21%</td> <td>Sunscreen</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn. 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>Warnings For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water-resistant sunscreen if swimming or sweating. 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: <ul style="list-style-type: none"> Limit time in the sun, especially from 10a.m.-2p.m. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months of age: ask a doctor. <p>Inactive ingredients Water (Aqua), Caprylic/Capric Triglyceride, Coconut Alkanes, Cetearyl Alcohol, Glycerin, Aloe Barbadensis Leaf Juice, Glyceryl Stearate, PEG-100 Stearate, Coco-Glucoside, Helianthus Annuus (Sunflower) Seed Oil, Sodium Phytate, Alcohol, Caprylyl/Capryl Glucoside, Sclerotium</p>	Active ingredients	Purpose	Zinc Oxide 21%	Sunscreen	<p>Drug Facts (continued)</p> <p>Gum, Xanthan Gum, Polyhydroxystearic Acid, Polyglyceryl-3 Polynicotinate, Isostearic Acid, Lecithin, Pyrus Malus (Apple) Fruit Extract, Cetearyl Glucoside, Tetrahexyldecyl Ascorbate, Butyrospermum Parkii (Shea) Butter, Coco-Caprylate/Caprate, Tocopherol, Sodium Hyaluronate, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide, C13-14 Isoparaffin, Laureth 7, Hydrolyzed Jojoba Esters, Citric Acid, Anthemis Nobilis Flower Extract, Calendula Officinalis Flower Extract, Camellia Sinensis (Green Tea) Extract, Triethoxycaprylylsilane, Dimethicone, Fragrance, Limonene, Linalool, May contain +/- Mica (CI 77019), Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499).</p> <p>Other information Protect the product in this container from excessive heat and direct sun.</p> <ul style="list-style-type: none"> DERMATOLOGICALLY TESTED PARABEN FREE GLUTEN FREE VEGAN CERTIFIED CRUELTY FREE <p>FLOETIC BEAUTY LLC, DIST. CLYDE HILL, WA 98004</p> <p>MADE IN USA FLOETICBEAUTY.COM</p>	<p>BE UNSTOPPABLE REFILLABLE BB CREAM BROAD SPECTRUM SPF 25</p> <p style="text-align: center;">F L O E T I C</p> <p>0.67 fl oz / 20 ml</p>	<p>BE UNSTOPPABLE Breathable and layerable</p> <p>PROTECT UVA/UVB broad spectrum SPF 25 protection</p> <p>HYDRATE Aloe and sunflower oil provide soothing moisture</p> <p>NOURISH Antioxidant-rich with vitamin C, vitamin E and green tea extracts</p>
Active ingredients	Purpose						
Zinc Oxide 21%	Sunscreen						
MEDIUM 01							

BB CREAM BROAD SPECTRUM SPF 25 MEDIUM 01

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4180
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	210 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
COCO GLUCOSIDE (UNII: ICS790225B)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ALCOHOL (UNII: 3K9958V90M)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
ISO STEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
APPLE (UNII: B423VGH5S9)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4180-2	1 in 1 CARTON	12/09/2019	
1	NDC:62742-4180-1	20 mL in 1 BOTTLE; 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	11/21/2019	

Labeler - Allure Labs Inc (926831603)

Revised: 11/2019

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