

I CONCEAL FLAWLESS FOUNDATION BROAD SPECTRUM SPF 30 SUNSCREEN MAHOGANY- zinc oxide and titanium dioxide cream

Allure Labs

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

Titanium Dioxide 6.5%

Zinc Oxide 8.5%

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

Directions For Sunscreen Use • Apply generously 15 minutes before sun exposure. • Children under 6 months of age: ask a doctor. • 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 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.

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

Inactive Ingredients Water/Aqua/Eau, Coconut Alkanes, Cyclopentasiloxane, Squalane,

Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Glycerin, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Isohexadecane, Polyglyceryl-4 Isostearate, Vinyl Dimethicone/Lauryl Dimethicone Crosspolymer, Hydrogen Dimethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Dimethicone, Alumina, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cyclohexasiloxane, Magnesium Sulfate, Mica, Polyhydroxystearic Acid, Phenoxyethanol, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Caprylyl Glycol, Dimethicone/PEG-10/15 Crosspolymer, Etylhexylglycerin, Hexylene Glycol, Dipotassium Glycyrrhizate, Perfluorodecalin, Zinc PCA, Saccharomyces Lysate Extract, Centella Asiatica Extract, Leuconostoc/Radish Root Ferment Filtrate, Olea Europaea (Olive) Leaf Extract, Artemisia Vulgads Extract, Hyaluronic Acid, Laminaria Digitata Extract, Phospholipids, Isomalt, Cyperus Rotundus Root Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Xanthium Sibiricum Fruit Extract, Dipropylene Glycol, Retinyl Palmitate, Ascorbyl Palmitate, Tocopheryl Acetate, Opuntia Ficus-Indica Stem Extract, Sodium Citrate, Sodium Benzoate, Beta-Carotene, Potassium Sorbate, Salicylic Acid, Acetyl Hexapeptide-8, Sorbic Acid, Tocopherol, Lecithin, Vitis Vinifera (Grape) Fruit Cell Extract, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Ergothioneine, Iron Oxides (CI 77492), Bismuth Oxochloride (CI 77163), Iron Oxides (CI 77491), Iron Oxides (CI 77499)

<p>Drug Facts (continued)</p> <p>Other Information</p> <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun. <p>Inactive Ingredients</p> <p>Water/Aqua/Eau, Coconut Alkanes, Cyclohexasiloxane, Stearic Acid, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Glycerin, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Isohexadecane, Polyglyceryl-4 Isostearate, Vinyl Dimethicone/Lauryl Dimethicone Crosspolymer, Hydrogen Dimethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Dimethicone, Alumina, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cyclohexasiloxane, Magnesium Sulfate, Mica, Polyhydroxystearic Acid, Phenoxyethanol, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Caprylyl Glycol, Dimethicone/PEG-10/15 Crosspolymer, Etylhexylglycerin, Hexylene Glycol, Dipotassium Glycyrrhizate, Perfluorodecalin, Zinc PCA, Saccharomyces Lysate Extract, Centella Asiatica Extract, Leuconostoc/Radish Root Ferment Filtrate, Olea Europaea (Olive) Leaf Extract, Artemisia Vulgads Extract, Hyaluronic Acid, Laminaria Digitata Extract, Phospholipids, Isomalt, Cyperus Rotundus Root Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Xanthium Sibiricum Fruit Extract, Dipropylene Glycol, Retinyl Palmitate, Ascorbyl Palmitate, Tocopheryl Acetate, Opuntia Ficus-Indica Stem Extract, Sodium Citrate, Sodium Benzoate, Beta-Carotene, Potassium Sorbate, Salicylic Acid, Acetyl Hexapeptide-8, Sorbic Acid, Tocopherol, Lecithin, Vitis Vinifera (Grape) Fruit Cell Extract, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Ergothioneine, Iron Oxides (CI 77492), Bismuth Oxochloride (CI 77163), Iron Oxides (CI 77491), Iron Oxides (CI 77499).</p> <p>Questions? Call 800-796-7516</p> <p>Manufactured for IMAGE Skincare, Lantana, FL 33462 USA Manufactured in USA from globally sourced ingredients and components www.imageskincare.com</p> <p>IC-208-80X-V1</p>	<p style="text-align: center;">I</p> <p style="text-align: center;">IMAGE SKINCARE</p> <p style="text-align: center;">I CONCEAL</p> <p style="text-align: center;">flawless foundation fond de teint impeccable</p> <p style="text-align: center;">broad spectrum SPF 30 sunscreen écran solaire à large spectre FPS 30</p> <p style="text-align: center;">MAHOGANY / ACAJOU</p> <p style="text-align: center;">Net wt. 1 oz / 28 g</p>	<p style="text-align: center;">Protect and perfect for flawless skin</p> <ul style="list-style-type: none"> All-mineral, broad-spectrum UVA and UVB protection with zinc oxide and titanium dioxide Mineral pigments blend seamlessly to provide a full-coverage finish Plant stem cells, antioxidants and skin-conditioning botanicals nourish the skin Covers the appearance of redness after cosmetic procedures Minimizes the look of pores and imperfections <p style="text-align: center;">DIRECTIONS: Apply desired amount to face and neck and blend.</p> <p style="text-align: center;">Get to know I BEAUTY at www.imageskincare.com</p> <p style="text-align: center;">I BEAUTY</p>	<p style="text-align: center;">Physician formulated Oxybenzone free Paraben free</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Titanium Dioxide 6.5% ...</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide 8.5%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> 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. <p>Warnings</p> <ul style="list-style-type: none"> For external use only. <p>Do not use</p> <ul style="list-style-type: none"> On damaged or broken skin. <p>When using this product</p> <ul style="list-style-type: none"> Keep out of eyes. Rinse with water to remove. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> Rash occurs. <p>Keep out of reach of children.</p> <ul style="list-style-type: none"> If swallowed, get medical help or contact a Poison Control Center right away. <p>Directions For Sunscreen Use</p> <ul style="list-style-type: none"> Apply generously 15 minutes before sun exposure. Children under 6 months of age: ask a doctor. 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 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: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. to 2 p.m. wear long-sleeved shirts, pants, hats and sunglasses. 	Active Ingredients	Purpose	Titanium Dioxide 6.5% ...	Sunscreen	Zinc Oxide 8.5%	Sunscreen
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zinc oxide and titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:62742-4214

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	85 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	65 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
PERFLUNAFENE (UNII: 54A06VV62N)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
XANTHIUM SIBIRICUM FRUIT (UNII: 3H333L84C2)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OPUNTIA FICUS-INDICA STEM (UNII: MUD8892KHL)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
BETA CAROTENE (UNII: 01YAE03M7J)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWL)	
SORBIC ACID (UNII: X045WJ989B)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	

HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)
WATER (UNII: 059QF0KO0R)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
VITIS VINIFERA ANTHOCYANINS (UNII: F02KPB2508)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
TRIETHOXYSIPLYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
LAMINARIA DIGITATA (UNII: 15E7C67EE8)
ISOMALT (UNII: S870P55O2W)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MICA (UNII: V8A1AW0880)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)
DIMETHICONE (UNII: 92RU3N3Y1O)
ALUMINUM OXIDE (UNII: LMI26O6933)
SQUALANE (UNII: GW89575KF9)
HYALURONIC ACID (UNII: S270N0TRQY)
TOCOPHEROL (UNII: ROZB2556P8)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4214-2	1 in 1 CARTON	04/18/2022	
1	NDC:62742-4214-1	28 g 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	04/18/2022	

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4214)

