

**MD RESTORING DAILY DEFENSE MOISTURIZER SPF 50- zinc oxide and titanium dioxide 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.*

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**Drug Facts**

Active ingredients

Titanium Dioxide 6.5%

Zinc Oxide 8.7%

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 • 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 • 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 value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 am.-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 Ingredient:

CYCLOPENTASILOXANE, AQUA/WATER/EAU, C12-15 ALKYL BENZOATE, DIMETHICONE, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, GLYCERIN, ALUMINUM HYDROXIDE, STEARIC ACID, DIMETHICONE/PEG-10/15 CROSSPOLYMER, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, SODIUM CHLORIDE, CETYL PEG/PPG-10/1 DIMETHICONE, HEXYL LAURATE, PEG/PPG-18/18 DIMETHICONE, POLYGLYCERYL-4

ISOSTEARATE, PHENOXYETHANOL, DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, LIMONENE, CAPRYLYL GLYCOL, CETEARYL OLIVATE, CYCLOHEXASILOXANE, SORBITAN OLIVATE, ETHYLHEXYL PALMITATE, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, CITRUS NOBILIS (MANDARIN ORANGE) PEEL OIL, PEG-8, TOCOPHERYL ACETATE, TOCOPHEROL, ISOMALT, BENZOIC ACID, DIPROPYLENE GLYCOL, PROPYLENE GLYCOL, BUTYLENE GLYCOL, VANILLA PLANIFOLIA FRUIT EXTRACT, SODIUM CITRATE, ASCORBYL PALMITATE, SILICA DIMETHYL Silylate, PENTYLENE GLYCOL, ASCORBIC ACID, CITRIC ACID, POLYGONUM AVICULARE EXTRACT, BAROSMA BETULINA LEAF OIL, CAESALPINIA SPINOSA FRUIT POD EXTRACT, CARBOMER, SODIUM LACTATE, SODIUM BENZOATE, POLYSORBATE 20, SODIUM HYALURONATE, LECITHIN, POTASSIUM SORBATE, VITIS VINIFERA (GRAPE) FRUIT CELL EXTRACT, HELIANTHUS ANNUUS (SUNFLOWER) SPROUT EXTRACT, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, SODIUM FERROCYANIDE, PALMITOYL TRIPEPTIDE-1, PALMITOYL TETRAPEPTIDE-7

**Drug Facts (continued)**

POLYGLYCERYL-4 ISOSTEARATE, PHENOXYETHANOL, DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, LIMONENE, CAPRYLYL GLYCOL, CETEARYL OLIVATE, CYCLOHEXASILOXANE, SORBITAN OLIVATE, ETHYLHEXYL PALMITATE, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, CITRUS NOBILIS (MANDARIN ORANGE) PEEL OIL, PEG-8, TOCOPHERYL ACETATE, TOCOPHEROL, ISOMALT, BENZOIC ACID, DIPROPYLENE GLYCOL, PROPYLENE GLYCOL, BUTYLENE GLYCOL, VANILLA PLANIFOLIA FRUIT EXTRACT, SODIUM CITRATE, ASCORBYL PALMITATE, SILICA DIMETHYL Silylate, PENTYLENE GLYCOL, ASCORBIC ACID, CITRIC ACID, POLYGONUM AVICULARE EXTRACT, BAROSMA BETULINA LEAF OIL, CAESALPINIA SPINOSA FRUIT POD EXTRACT, CARBOMER, SODIUM LACTATE, SODIUM BENZOATE, POLYSORBATE 20, SODIUM HYALURONATE, LECITHIN, POTASSIUM SORBATE, VITIS VINIFERA (GRAPE) FRUIT CELL EXTRACT, HELIANTHUS ANNUUS (SUNFLOWER) SPROUT EXTRACT, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, SODIUM FERROCYANIDE, PALMITOYL TRIPEPTIDE-1, PALMITOYL TETRAPEPTIDE-7.

**Questions?** call 800-796-7546

Manufactured for IMAGE Skincare, Lantana, FL 33462 USA. Manufactured in USA from globally sourced ingredients and components. www.imageSkincare.com

**clean clinical skincare™**

**PHYSICIAN-FORMULATED**  
Tried, true and tested by skincare professionals

- 100% mineral filters with SPF 50 broad-spectrum UVA and UVB protection
- A blend of UV filters and extracts help to defend against the effects of environmental stressors
- Perfect for everyday wear under makeup

**IMAGE MD**  
CLINICAL SKINCARE

**restoring daily defense moisturizer**  
SPF 50

**broad spectrum SPF 50 sunscreen**

**Drug Facts**

Active ingredients	Purpose
Titanium Dioxide 6.5%	Sunscreen
Zinc Oxide 8.7%	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** • 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. • **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**  
CYCLOPENTASILOXANE, AQUA/WATER(EAU), C12-15 ALKYL BENZOATE, DIMETHICONE, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, GLYCERIN, ALUMINUM HYDROXIDE, STEARIC ACID, DIMETHICONE/PEG-10/15 CROSSPOLYMER, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, SODIUM CHLORIDE, CETYL PEG/PPG-10/1 DIMETHICONE, HEXYL LAURATE, PEG/PPG-18/18 DIMETHICONE.

PHYSICIAN FORMULATED

Net wt. 2 oz / 57 g

## MD RESTORING DAILY DEFENSE MOISTURIZER SPF 50

zinc oxide and titanium dioxide cream

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:62742-4220

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.7 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MANDARIN OIL (UNII: NJO720F72R)	
AGATHOSMA BETULINA LEAF OIL (UNII: KOS935A04V)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
VANILLA (UNII: Q74T35078H)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
VITIS VINIFERA ANTHOCYANINS (UNII: F02KPB2508)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
SODIUM FERROCYANIDE (UNII: 5HT6X21AID)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9)	

<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>TRIETHOXYSIPLYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE</b> (UNII: X75PL53TZJ)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>ISOMALT</b> (UNII: S870P55O2W)
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4220-1	7 g in 1 TUBE; Type 0: Not a Combination Product	10/21/2022	
2	NDC:62742-4220-3	1 in 1 CARTON	10/21/2022	
2	NDC:62742-4220-2	57 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	M020	10/21/2022	

**Labeler** - Allure Labs Inc (926831603)

**Registrant** - Allure Labs Inc (926831603)

### Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs Inc		926831603	manufacture(62742-4220)

