

JOSIE MARAN ARGAN DAILY MOISTURIZER SPF47 PROTECT AND PERFECT RADIANCE- zinc oxide, titanium dioxide lotion

Autumn Harp, 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.

Josie Maran Argan Daily Moisturizer SPF47 Protect and Perfect Radiance

Drug Facts

☐Active Ingredients

Zinc Oxide 9.4%**

Titanium Dioxide 5.9%**

☐Purpose

Sunscreen

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.

Stop use and ask a doctor if rash occurs.

When using this product

- keep out of eyes
- Rinse with water to remove

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
- 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 the 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 10am - 2pm.
- Wear long-sleeve shirts, pants, hats, and sunglasses

☐ Inactive Ingredients :

Aqua (Water)**, Caprylic/Capric Triglyceride**, Ethylhexyl Palmitate**, Titanium Dioxide**, Cyclopentasiloxane, Argania Spinosa (Argan) Kernel Oil**, Polyglyceryl-6 Polyricinoleate**, Mica**, Nylon-12, Glycerin**, Polyhydroxystearic Acid, Polyglyceryl-2 Isostearate, Methicone, Alumina, Phenoxyethanol, Isononyl Isononanoate, Disteardimonium Hectorite, Tocopheryl Acetate, Triethoxycaprylylsilane, Polysilicone-11, Sodium Chloride**, Iron Oxide (CI 77492)**, Bismuth Oxychloride, Magnesium Stearate**, Isopropyl Myristate, Fragrance**, Bisabolol, Iron Oxides (CI 77491)**, Cochineal, Aloe Barbadensis Leaf Juice*, Simmondsia Chinensis (Jojoba) Seed Oil*, Tin oxide (CI 77861)**, Isopropyl Titanium Triisostearate, Iron Oxides (CI 77499)**, Stearalkonium Hectorite, Propylene Carbonate, Laureth-12, Camellia Sinensis (Green Tea) Leaf Extract**, Tocopherol**, Ethylhexylglycerin, Citric Acid**, Potassium Sorbate**, Sodium Benzoate**.

* Organic ** Natural

☐ Other Information:

- Protect this product from excessive heat and direct sun.

Principle Display Panel

Drug Facts (continued)

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 am – 2 pm
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Inactive Ingredients: Aloe Barbadensis Leaf**, Caprylic/Capric Triglyceride**, Aqua (Water)**, Ethylhexyl Palmitate**, Mica**, Cyclopentasiloxane, Argania Spinosa (Argan) Kernel Oil**, Polyglyceryl-6 Polyricinoleate, Titanium Dioxide, Nylon-12, Glycerin**, Polyhydroxystearic Acid, Polyglyceryl-2 Isostearate, Methicone, Alumina, Phenoxyethanol, Isononyl Isononanoate, Tocopheryl Acetate, Distearaldimonium Hectorite, Polysilicone-11, Iron Oxide (CI 77492)**, Bismuth Oxychloride, Sodium Chloride**, Magnesium Stearate**, Isopropyl Myristate, Parfum (Fragrance)**, Iron Oxides (CI 77491)**, Bisabolol, Simmondsia Chinensis (Jojoba) Seed Oil*, Camellia Sinensis (Green Tea) Leaf Extract**, Ethylhexylglycerin, Potassium Sorbate**, Sodium Benzoate**, Citric Acid**.

MAY CONTAIN CARBONE AS A COLOR ADDITIVE.
*ORGANIC **NATURALLY-DERIVED

Other information:

- protect this product from excessive heat and direct sun

Distributed by Josie Maran Cosmetics, LLC
Hollywood, CA 90038
Made in U.S.A.
josiemaran.com

JOSIE MARAN
Argan Daily Moisturizer SPF 47

Protect + Perfect

Radiance

broad spectrum
SPF 47
and SunBoost ATB™

120 mL 4 fl. oz.

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 5.9%*	Sunscreen
Zinc Oxide 9.4%**	Sunscreen

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Drug Facts (continued)

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- Limit time in the sun, especially from 10 a.m. – 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Aloe Barbadensis Leaf Juice**, Caprylic/Capric Triglyceride**, Aqua/Water**, Ethylhexyl Stearate**, Mica**, Cycloheximide, Arginine Spongia (Mangrove) Oil**, Polysiloxane-6 Polynorbornene, Titanium Dioxide, Nylon-12 Glycol**, Polyhydroxyester Acid, Polyglycol-2 Isostearate, Methicone, Moringa, Phenylethylol, Triethylcaprylylsilane, Ironoxy Ironoxide, Tocopherol Acetate, Dibutylsebacate, Polylicane-11, Iron Oxide (CI 77492), Benzyl Glycolate, Sodium Chloride**, Magnesium Stearate**, Isocetyl Myristate, Parfum (Fragrance)**, Iron Oxide (CI 77491), Biotinyl, Simmondsia (Jojoba) Seed Oil**, Camellia, Iron Oxide (CI 77499)**, Isopropyl Titanium Triacetate, Tin Oxide, Stearalkonium Hectorite, Propylene Carbonate, Laureth-12, Camellia Oleic Acid (Green Tea) Leaf Extract**, Ethylhexylglycerin, Potassium Sorbate**, Sodium Benzoate**, Citric Acid**, NY-COYVAN CARBINE AS A COLOR ADJUTIVE.

*ORGANIC. **NATURALLY DERIVED.

Other Information

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Questions or Comments

Call toll free 1-855-461-6512.

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josiemaran.com



JOSIE MARAN

Argan Daily Moisturizer SPF 47

Protect + Perfect
Radiance

broad spectrum
SPF 47 and
SunBoost ATB™

177 mL 6 fl. oz.

Drug Facts

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Titanium Dioxide 5.9%*	Sunscreen
Zinc Oxide 9.4%*	Sunscreen

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Drug Facts (continued)

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Inactive Ingredients
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 *ORGANIC **NATURALLY-DERIVED

Other information
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JOSIE MARAN
 Argan Daily Moisturizer SPF 47

Protect + Perfect
 Radiance

broad spectrum
 SPF 47 and
 SunBoost ATB™

60 mL 2 fl. oz.

Drug Facts

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zinc oxide, titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0355
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9.4 mg in 100 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.9 mg in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
ETHYLHEXYL PALMITATE (UNII: 2865993309)			
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)			
POLYGLYCERYL-6 DIOLEATE (UNII: 062SZD3F3X)			
MICA (UNII: V8A1AW0880)			
ARGAN OIL (UNII: 4V59G5UW9X)			
NYLON-12 (UNII: 446U8J075B)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			

POLYGLYCERYL-2 MONOISO STEARATE (UNII: 7B8OE71MQC)
METHICONE (20 CST) (UNII: 6777U11MKT)
ALUMINUM OXIDE (UNII: LM26O6933)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYSILICONE-15 (UNII: F8DRP5BB29)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MAGNESIUM STEARATE (UNII: 70097M6I30)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
APRICOT (UNII: 269CJD5GZ9)
LEVOMENOL (UNII: 24WE03BX2T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
JOJOBA OIL (UNII: 724GKU717M)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ISOPROPYL TITANIUM TRIISO STEARATE (UNII: 949E3KBJ1I)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)
LINALOOL, (+)- (UNII: F4VNO44C09)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
LAURETH-12 (UNII: OAH19558U1)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CITRIC ACID ACETATE (UNII: DSO12WL7AU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
TOCOPHEROL (UNII: R0ZB2556P8)
.BETA.-BISABOLOL (UNII: LP618AV2EA)
COCHINEAL (UNII: TZ8Z31B35M)
STANNIC OXIDE (UNII: KM7N50LOS6)
FARNESOL (UNII: EB41QIU6JL)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0355-1	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/24/2014	
2	NDC:51514-0355-2	120 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/24/2014	
3	NDC:51514-0355-3	15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/24/2014	
4	NDC:51514-0355-4	177 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/24/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/24/2014	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0355)

Revised: 10/2019

Autumn Harp, Inc.