

BLUE MONARCH TINTED SPF-50 (ROSE GOLD)- zinc oxide cream
Blue Monarch, LLC

BLUE MONARCH Tinted SPF-50 (Rose Gold)

Drug Facts

Active Ingredients

Zinc Oxide 18.00%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection
- 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 or irritation develops and

Keep out of reach of children.

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

If pregnant or breast-feeding,

ask a health professional before use

Directions:

- Apply liberally 15 minutes before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.
- Reapply at least every 2 hours

- Use a water-resistant sunscreen if swimming or sweating
- Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including: **Sun Protection Measures.**
- 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

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, C18-21 Alkane, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl Glycol, Citric Acid, Citrullus Lanatus (Watermelon) Extract, Cocos Nucifera (Coconut) Oil, Decyl Glucoside, Dodecane, Glycerin, Glyceryl Laurate, Glyceryl Stearate, Glyceryl Undecylenate, Iron Oxides (Black, Red, Yellow), Mangifera Indica (Mango) Butter, Punica Granatum (Pomegranate) Extract, Ricinus Communis (Castor) Oil, Sorbitan Stearate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Vaccinium Angustifolium (Blueberry) Extract, Xanthan Gum, Zemea (Corn) Propanediol.

Questions?

(617) 943-0951

Package Labeling:



Blue
MONARCH®

Tinted SPF-50

Rose Gold

35 mL (1.18 fl.oz.)



BLUEMONARCH.COM
CustomerCare@MyBlueMonarch.com

DISTRIBUTED BY:
Blue Monarch, LLC.
483 Boston Post Road
Weston, MA 02493
Product of USA

Drug Facts

Active Ingredients	Purpose
Zinc Oxide 18.00%	Sunscreen

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- Helps prevent sunburn.
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- Reapply at least every 2 hours
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- **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 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-sleeved shirts, pants, hats, and sunglasses.

Other Information:

Inactive Ingredients Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, C18-21 Alkane, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl Glycol, Citric Acid, Citrullus Lanatus (Watermelon) Extract, Cocos Nucifera (Coconut) Oil, Decyl Glucoside, Dodecane, Glycerin, Glyceryl Laurate, Glyceryl Stearate, Glyceryl Undecylenate, Iron Oxides (Black, Red, Yellow), Mangifera Indica (Mango) Butter, Punica Granatum (Pomegranate) Extract, Ricinus Communis (Castor) Oil, Sorbitan Stearate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Vaccinium Angustifolium (Blueberry) Extract, Xanthan Gum, Zemea (Corn) Propanediol.

Questions? (617) 943-0951



Please recycle this box

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Other Information: <ul style="list-style-type: none"> Protect the product in this container from excessive heat and direct sun. 	
Inactive Ingredients Aloe Barbadosensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, C18-21 Alkane, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl Glycol, Citric Acid, Citrullus Lanatus (Watermelon) Extract, Cocos Nucifera (Coconut) Oil, Decyl Glucoside, Dodecane, Glycerin, Glyceryl Laurate, Glyceryl Stearate, Glyceryl Undecylenate, Iron Oxides (Black, Red, Yellow), Mangifera Indica (Mango) Butter, Punica Granatum (Pomegranate) Extract, Ricinus Communis (Castor) Oil, Sorbitan Stearate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Vaccinium Angustifolium (Blueberry) Extract, Xanthan Gum, Zemea (Corn) Propanediol.	
Questions? Insert phone number (XXX) XXX-XXXX	

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Questions? Insert phone number (XXX) XXX-XXXX	

BLUE MONARCH TINTED SPF-50 (ROSE GOLD)

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72101-419
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	180 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SHEA BUTTER (UNII: K49155WL9Y)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
C18-C21 ALKANE (UNII: 33822S0M40)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
WATERMELON (UNII: 231473QB6R)
COCONUT OIL (UNII: Q9L0O73W7L)
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)
DODECANE (UNII: 11A386X1QH)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL LAURATE (UNII: Y98611C087)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
FERRIC OXIDE RED (UNII: 1K09F3G675)
MANGO (UNII: I629I3NR86)
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)
CASTOR OIL (UNII: D5340Y2I9G)
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)
STEARIC ACID (UNII: 4ELV7Z65AP)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BLUEBERRY (UNII: 253RUG1X1A)
XANTHAN GUM (UNII: TTV12P4NEE)
CORN (UNII: 0N8672707O)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72101-419-00	1 in 1 BOX	08/07/2023	
1		35 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 Drug	M020	08/07/2023	

Labeler - Blue Monarch, LLC (080991096)