MIAMI MD SUN SHIELD BROAD SPECTRUM SPF 40- avobenzone, homosalate, octisalate, octocrylene cream BRAND BOLT LLC

MIAMI MD SUN SHIELD Broad Spectrum SPF 40

Drug Facts

Active Ingredients

Avobenzone 3.00% Homosalate 9.00% Octisalate 5.00% Octocrylene 6.00%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- If used as directed with other sun protection measures (see), decreases the risk of skin cancer and early skin aging caused by the sun. **Directions**

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 lasts.

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.

Other Information:

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

Inactive Ingredients:

Aqua (Deionized Water), Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Glyceryl Stearate Citrate, Caprylic/Capric Triglyceride, Zemea (Corn) Propanediol, Polysorbate-20, Cetearyl Alcohol, Cetearyl Glucoside, Cyclopentasiloxane, Bis-Vinyl Dimethicone/Dimethicone Copolymer, Phenoxyethanol, Ethylhexylglycerin, Ascorbyl Palmitate (Vitamin C), Rosa Damascena (Rose) Extract, Musa Sapientum (Banana) Extract, Cocos Nucifera (Coconut) Oil, Sodium Hyaluronate, Glycyrrhiza Glabra (Licorice) Extract, C12-15 Alkyl Benzoate, Tetrahexyldecyl Ascorbate (Vitamin C), Actinidia Chinensis (Kiwi) Extract, Niacinamide, Citric Acid, Glycerin, Jasminum Officinale (Jasmine) Extract, Tocopheryl Acetate (Vitamin E), Magnesium Aluminum Silicate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Astaxanthin.

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 sunm especially from 10 a.m. 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Questions?

1-844-829-8772

Package Labeling:

Drug Facts (continued)

Inactive Ingredients:

Agua (Deionized Water), Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Glyceryl Stearate Citrate, Caprylic/Capric Triglyceride, Zemea (Corn) Propanediol, Polysorbate-20, Cetearyl Alcohol, Cetearyl Glucoside, Cyclopentasiloxane, Bis-Viny Dimethicone/Dimethicone Copolymer, Phenoxyethanol, Ethylhexylglycerin, Ascorbyl Palmitate (Vitamin C), Rosa Damascena (Rose) Extract, Musa Sapientum (Banana) Extract, Cocos Nucifera (Coconut) Oil, Sodium Hyaluronate, Glycyrrhiza Glabra (Licorice) Extract, C12-15 Alkyl Benzoate, Tetrahexyldecyl Ascorbate (Vitamin C), Actinidia especially from 10 a.m. - 2 p.m. Chinensis (Kiwi) Extract, Niacinamide, Citric Acid, Glycerin, Jasminum Officinale (Jasmine) Extract, Tocophery Acetate (Vitamin E), Magnesium Aluminum Silicate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate

Copolymer, Astaxanthin.

Drug Facts (continued)

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.

■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,
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Manufactured for:

Miami MD 1900 Midway Lane, Smyrna, TN 37167

Questions?

1-844-829-8772

Miami**M**🤊

Sun Shield

Sunscreen

Broad-Spectrum

SPF 40

For Face & Hands

Drug Facts

Active Ingredients Purpose Avobenzone 3.00% Sunscreen Homosa ate 9.00% Sunscreen Octisalate 5.00% Sunscreen Octocrylene 6.00 % 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 lasts.

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.

Other Information:

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

30ml/1 fl. oz.

MIAMI MD SUN SHIELD BROAD SPECTRUM SPF 40

avobenzone, homosalate, octisalate, octocrylene cream

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:83140-373

TOPICAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CORN (UNII: 0N86727070)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BANANA (UNII: 4AJZ4765R9)	
COCONUT OIL (UNII: Q9L0O73W7L)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
KIWI FRUIT (UNII: 71ES77LGJC)	
NIACINAMIDE (UNII: 25X5118RD4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ASTAXANTHIN (UNII: 8XPW32PR7I)	

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:83140-373- 00	1 in 1 CARTON	12/05/2022		
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing II	larketing Information		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M020	12/05/2022	

Labeler - BRAND BOLT LLC (118171618)

Revised: 11/2023 BRAND BOLT LLC